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Report to Congressional Requesters

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FOOD SAFETY AND QUALITY

Who Does What in the Federal Government

GAO

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Resources, Community, and
Economic Development Division

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The Honorable Patrick J. Leahy
Chairman, Committee on Agriculture,
Nutrition and Forestry
United State Senate

The Honorable Tom Harkin
United States Senate

The Honorable Dennis E. Eckart
House of Representatives

This is the second volume of our report to you in response to your requests for information on the federal agencies involved with food safety and quality activities. In the first volume, also entitled Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A), we presented a brief summary of the results of our review. This report contains a more detailed description of the food safety and quality activities of the 12 federal agencies discussed in the first volume.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of Agriculture; the Secretary of Commerce; the Secretary of Health and Human Services; the Commissioner, Food and Drug Administration; the Administrator, Environmental Protection Agency; and other interested parties. Please call me on (202) 275-5138 if you have any questions concerning the report. Other major contributors to this report are listed in appendix I.

John W. Harman
Director, Food and
Agriculture Issues

Preface

This is a companion to Volume A, Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A), which summarizes information concerning federal agency food safety and quality activities. This volume, arranged by agency, contains a more detailed description of the food safety and quality activities of the 12 federal agencies discussed in the first volume.

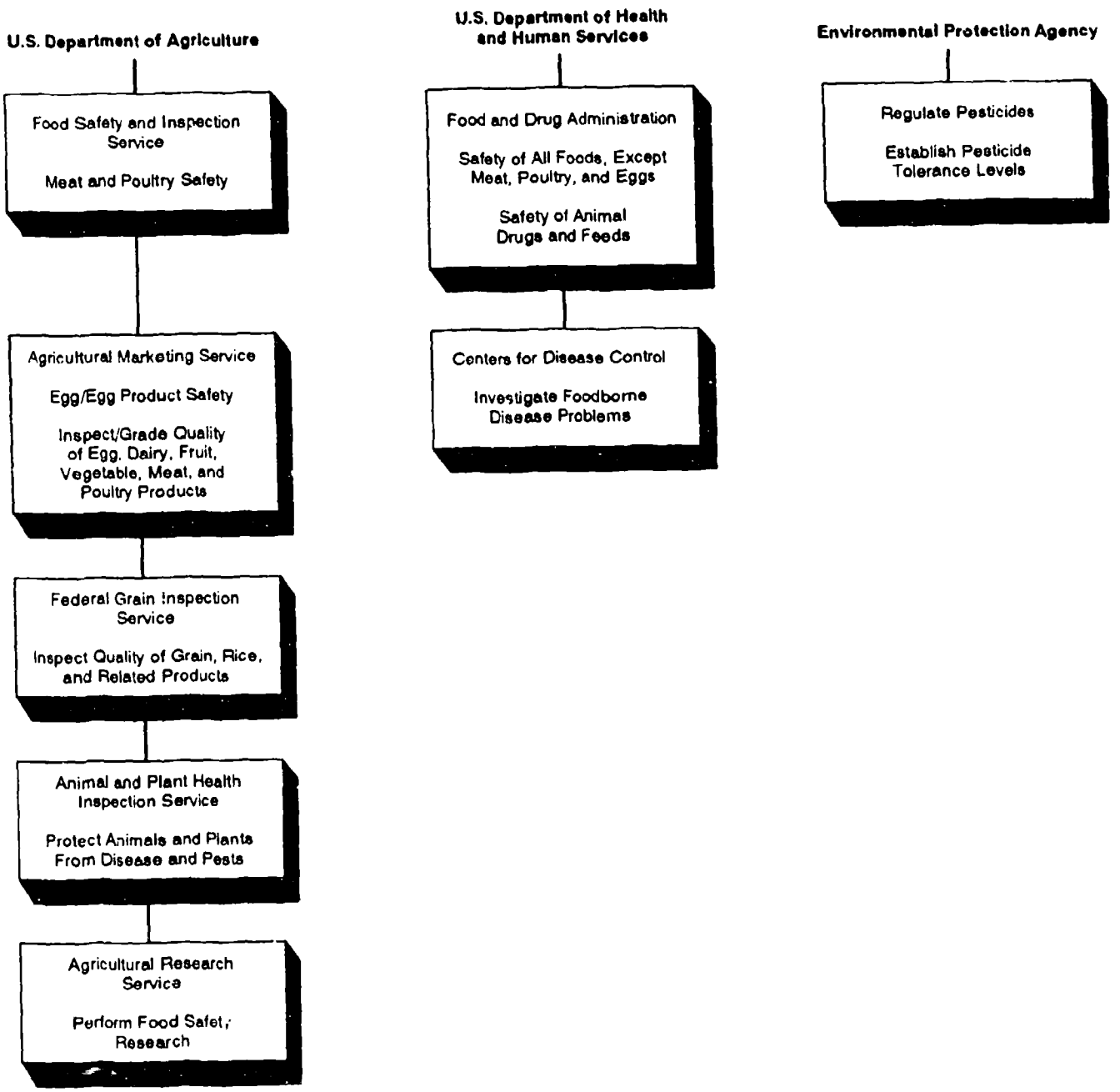
For the purposes of our review, we defined food safety activities as those carried out to assure that food is safe, sanitary, wholesome, and properly labeled. Food quality activities are defined as those establishing standards of quality and condition, grading food products according to the standards, certifying that food products meet the standards, and inspecting food products for compliance with the standards.

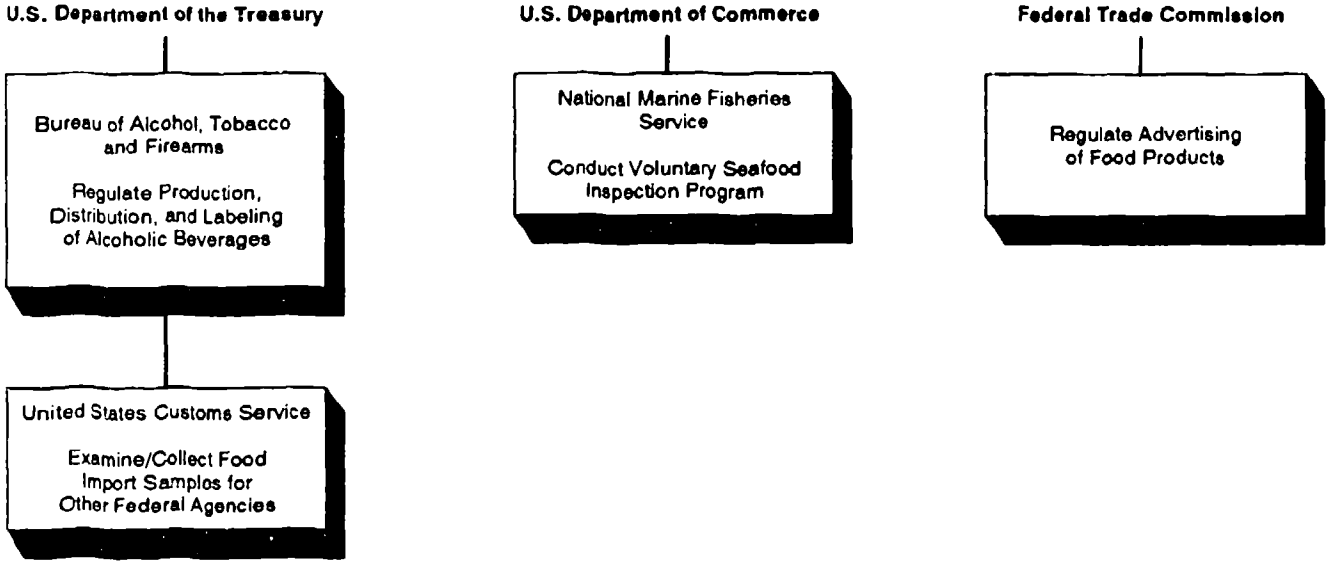
The six principal agencies are the Food and Drug Administration of the U.S. Department of Health and Human Services (HHS); Agricultural Marketing Service, Federal Grain Inspection Service, and Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA); the Environmental Protection Agency; and the National Marine Fisheries Service of the U.S. Department of Commerce. For these agencies, detailed information is included on (1) major legislation, (2) organizational units and responsibilities, (3) program activities, (4) funding levels, (5) staffing levels, (6) agreements with other federal agencies, and (7) critical food safety and quality issues of the 1990s.

Also, although we requested that the agencies provide funding, staffing, and workload data for fiscal years 1980 through 1989, some agencies did not provide certain data for each of these years because of changes in organization and/or responsibilities or because the data were destroyed pursuant to agency records retention guidelines. Consequently, some tables in this report do not include data back to fiscal year 1980. We did not convert the dollar amounts in the tables in this volume to constant dollars.

The six other federal agencies that play an important, but less significant, role in helping to ensure food safety and quality are USDA's Agricultural Research Service and Animal and Plant Health Inspection Service, the Department of the Treasury's Bureau of Alcohol, Tobacco and Firearms and United States Customs Service; HHS' Centers for Disease Control; and the Federal Trade Commission. For these agencies, information similar to that for the six principal agencies is presented, but in less detail.

Figure 1: Federal Agency Food Safety and Quality Responsibilities




U.S. Department of the Treasury
Bureau of Alcohol, Tobacco and Firearms
Regulate Production, Distribution, and Labeling of Alcoholic Beverages
United States Customs Service
Examine/Collect Food Import Samples for Other Federal Agencies
U.S. Department of Commerce
National Marine Fisheries Service
Conduct Voluntary Seafood Inspection Program
Federal Trade Commission
Regulate Advertising of Food Products

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Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ATF	Bureau of Alcohol, Tobacco and Firearms
CDC	Centers for Disease Control
CSRS	Cooperative State Research Service
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FGIS	Federal Grain Inspection Service
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GAO	General Accounting Office
HHS	Department of Health and Human Services
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
OPP	Office of Pesticide Programs
PPIA	Poultry Products Inspection Act
PUFI	Packed Under Federal Inspection
USDA	U.S. Department of Agriculture
USGSA	U.S. Grain Standards Act

Food and Drug Administration Activities Relating to Food Safety and Quality

The Food and Drug Administration (FDA) is responsible for ensuring that domestic and imported food products (except meat and poultry products) are safe, sanitary, nutritious, and wholesome; and are honestly labeled. The U.S. Department of Agriculture (USDA) has jurisdiction over meat and poultry products and shares responsibility for egg products with FDA.

Major Legislation

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.), is the major law relating to FDA's food safety and quality activities.

Federal Food, Drug, and Cosmetic Act

The FFDCA authorizes FDA to (1) regulate food (except meat and poultry products) production and manufacturing to ensure that food is safe, clean, and wholesome and (2) establish reasonable standards of identity, quality, and fill of container for food products. The act also (1) requires FDA to review and approve food and color additives before they can be marketed and (2) prohibits the interstate commerce of adulterated foods and false or misleading labeling of food products. A food is adulterated if it contains substances that may render it injurious to health. A food is misbranded if information required by law does not clearly appear on the label.

The act also directs FDA to maintain surveillance of all animal drugs, feeds, and veterinary devices marketed in interstate commerce to ensure their compliance with the act. The act requires that all animal drugs that are not generally recognized as safe and effective be approved by FDA before marketing on the basis of studies made by the sponsor. However, the act permits the export of an unapproved animal drug under certain conditions.

The act also mandates that FDA inspect every registered animal drug and medicated feed-manufacturing facility at least once every 2 years. FDA reviews the facilities, manufacturing procedures and controls, formulations, and labeling relating to marketed products to determine their compliance with the act and FDA regulations.

Other Legislation Affecting FDA's Food Safety Activities

Other laws affecting FDA's food safety activities include the

- Public Health Service Act, as amended (42 U.S.C. 201 et seq.);
- Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401 et seq.);
- Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.);

- Safe Drinking Water Act, as amended (21 U.S.C. 349);
- Infant Formula Act of 1980, as amended (21 U.S.C. 350a);
- Federal Anti-Tampering Act (18 U.S.C. 1365); and
- Federal Import Milk Act, as amended (21 U.S.C. 141).

The Public Health Service Act provides for federal/state cooperative assistance in preventing the interstate transmission of disease, and thus establishes FDA's authority for its programs for sanitation in milk processing, shellfish, restaurant and retail market operations, and interstate travel conveyances.

The Pesticide Monitoring Improvements Act requires FDA to (1) develop new, or modify existing, data management systems to track, summarize, and evaluate pesticide-monitoring data; (2) enter into cooperative agreements with foreign countries to obtain pesticide usage data on crops imported from those countries; and (3) develop an analytical methods research plan to guide the development of methods to improve the efficiency of food monitoring.

Under the Egg Products Inspection Act, the Agricultural Marketing Service (AMS) is responsible for inspecting egg product processing plants and firms marketing eggs, while FDA is responsible for inspecting restaurants, institutions, and food-manufacturing establishments that serve eggs or use them in their products.

The Safe Drinking Water Act requires FDA, in consultation with the Environmental Protection Agency (EPA), to establish regulations relating to bottled drinking water standards. Pursuant to the act, FDA has established standards of quality and current good manufacturing practice regulations for processing and bottling waters.

The Infant Formula Act of 1980 established nutrient requirements for infant formulas and gave FDA authority to establish requirements for quality control, record keeping, reporting, and recall procedures. The act also extended FDA's factory inspection authority to permit access to manufacturers' records and test results necessary to determine compliance.

The Federal Anti-Tampering Act provides for monetary penalties and imprisonment for tampering with consumer products, including food, and their labeling and packaging that affect interstate and foreign commerce. FDA is responsible for investigating violations of the act relating to products it regulates.

Under the Federal Import Milk Act, milk and cream may be imported into the United States only under a permit from the Secretary of Health and Human Services (HHS) after certain sanitary and other prerequisites have been fulfilled.

Organizational Units and Responsibilities

At FDA headquarters in the Washington, D.C., area, three main offices carry out food safety and quality activities—the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the Office of Regulatory Affairs.

The Center for Food Safety and Applied Nutrition carries out FDA's Food and Cosmetics Program. The Center (1) conducts and supports food safety research, (2) develops and oversees enforcement of food safety and quality regulations, (3) coordinates and evaluates FDA's surveillance and compliance programs relating to foods, (4) coordinates and evaluates federal/state cooperative programs relating to foods, and (5) develops and disseminates food safety and regulatory information to consumers and industry.

The Center for Veterinary Medicine carries out FDA's Animal Drugs and Feeds Program, which includes ensuring that drugs and feeds used in animals are safe, effective, and properly labeled; and produce no human health hazards when used in food-producing animals. It is also responsible for monitoring animal drug sales and distribution as well as good manufacturing practices associated with animal drug and medicated feed production.

The Office of Regulatory Affairs consists of a headquarters staff and FDA field offices. The headquarters staff oversees field office activities. Field offices conduct investigational and laboratory functions for all of FDA's major product areas—foods, human drugs, animal drugs and feeds, and medical devices and radiological products. Field office food safety and quality responsibilities include those relating to research, investigations, inspections, compliance, enforcement, and laboratory analyses.

FDA Field Facilities

In fiscal year 1989, FDA maintained offices and staff in 49 states, the District of Columbia, and Puerto Rico. FDA field facilities include 6 regional offices, 21 district offices, 18 district laboratories, and 136 resident posts.

The regional offices coordinate the activities of the various FDA offices in their regions and coordinate FDA activities with state authorities. The district offices serve as offices for investigators and compliance action staff and are the main control point for day-to-day operations. The district laboratories, located within the district offices, provide facilities to test products for safety and to conduct the research necessary to evaluate health hazards and to develop the means to detect product hazards and prevent them. Resident posts are smaller offices which serve as a base for investigators so that FDA can have investigative staff widely dispersed to respond to emergencies as well as to save investigational travel costs and time.

Program Activities

Manufacturers subject to FDA's jurisdiction are primarily responsible for ensuring the safety of their products. FDA's role is to monitor the food industry and to provide the consumer with the best assurances possible that the industry is meeting its responsibility. FDA characterizes its activities as primarily preventive rather than corrective. It does not have sufficient resources to continually police every segment of the food industry and the other industries it regulates. Its strategy, therefore, is designed to ensure that safety is built into products rather than to check for safety after products have been produced.

FDA has oriented its food inspection program to perform in-depth inspections of those firms producing commodities having a high potential for causing risks to health if established processes are not adequately controlled. FDA also expands its surveillance of the nation's food supply through cooperative relationships with state and local regulatory agencies.

The food safety and quality activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the Office of Regulatory Affairs are discussed below. Topics discussed include inspection activities, import activities, export activities, enforcement activities, and FDA's relationship to state inspection programs.

Center for Food Safety and Applied Nutrition Activities

The Center carries out the following 10 projects of FDA's Food and Cosmetics Program:

- Food Composition, Standards, Labeling, and Economics;
- Foodborne Biological Hazards;
- Diet/Toxicity Interaction;

- Molecular Biology and Natural Toxins;
- Pesticides and Chemical Contaminants;
- Risk Assessment Research and Policy Development;
- Food and Color Additive Petition Review and Policy Development;
- Colors and Cosmetics Technology;
- Postmarket Surveillance and Epidemiology; and
- Technical Assistance.

The following are brief descriptions of the Center's food safety and quality activities relating to the 10 projects.

Food Composition, Standards, Labeling, and Economics

This project's mission is intended to ensure that food quality and safety are maintained and/or improved through product formulation, processing, fortification, and other measures; informative food labeling is provided to consumers; the consumer is not economically harmed by misleading labeling or packaging; and product integrity is maintained through the development, promulgation, and enforcement of standards. Project activities include

- developing information on food composition, nutrition status, and biochemistry of food components;
- establishing guidelines and labeling standards for traditional foods and foods for special dietary use;
- developing and revising standards for food to ensure identity, quality, and fill of container; and
- investigating potential economic abuses and establishing and enforcing regulations to prevent or minimize such abuse.

Foodborne Biological Hazards

This project involves surveillance, enforcement, and prevention of foodborne safety problems that are caused by microbial contamination and adulteration by rodent, bird, and animal filth; and insect infestation. Its mission is to reduce the incidence of microbiological hazards, filth, decomposition, and foreign objects in the nation's food supply. Project activities include

- developing new procedures for use by FDA and other organizations to improve methods for isolating and identifying foodborne strains of pathogenic microorganisms;
- surveying various food commodities for the presence of newly defined microbial hazards to provide better ways of monitoring the food supply;
- inspecting food-manufacturing establishments and imported foods to identify and eliminate conditions due to filth, decomposition, and foreign objects that may cause a hazard to health;

- negotiating memorandums of understanding with foreign countries that export food to the United States regarding the certification that their food products were processed in accordance with manufacturing practices that provide adequate quality control; and
- conducting enforcement and surveillance operations with respect to sanitation practices of interstate conveyances (aircraft, buses, passenger trains, and vessels) and their support facilities handling food, water, and wastes.

Diet/Toxicity Interaction

This project's mission is intended to ensure that the safety and nutritional adequacy of foods are maintained and/or improved through identifying and evaluating nutrient toxicities and factors modifying them, impacts of toxic substances on nutrient requirements and functions, and impacts of diet and nutrients on toxic effects. Project activities include

- performing studies on the health effects of nutrient excess, such as high doses of vitamin A;
- evaluating the effects of nutrition and diet on toxicological endpoints, such as relating fiber intake and type to the development and progress of colon cancer; and
- studying the effects of toxicants on nutritional endpoints, such as the effects of tin on bone mineralization and on nerve function.

Molecular Biology and Natural Toxins

This project's mission is intended to conduct research appropriate to gaining a clear understanding of host-parasite interactions as they relate to foodborne microorganisms, to assess their true impact on public health, and to identify microbial attributes contributing to both acute and chronic disease processes. Project activities include

- applying biotechnology to determine the pathogenic attributes (those contributing to acute and chronic disease) possessed by foodborne microbes;
- studying the ecological, biological, and physical interactions, accumulation, stability, and chemical structure of marine toxins and evaluating their true impact on consumer health;
- developing and applying methodologies to better isolate and purify biologically active products of foodborne microbes so that their impact alone, and collective impacts, on host defenses can be assessed; and
- conducting basic research in microbial genetics.

Pesticides and Chemical Contaminants

This project's mission is intended to ensure that the consumer is protected against undue risk from pesticides and chemical contaminants in the food supply. Project activities include

- developing information to identify and evaluate pesticide and chemical contaminant problems;
- developing an analytical methodology for measuring trace amounts of pesticides and chemical contaminants in food;
- determining the frequency and level of occurrence of pesticides and chemical contaminants in the food supply, including field surveys and FDA's Total Diet Study;
- carrying out toxicologic studies to determine the toxic behavior of chemical contaminants and epidemiologic studies to determine the effects of chemical contaminants on humans;
- establishing regulatory limits for chemical contaminants in food, where appropriate; and
- carrying out field-monitoring programs for selected chemical contaminants in foods of dietary importance and taking regulatory action where warranted.

Risk Assessment Research and Policy Development

This project's mission includes providing information obtained from laboratory experimentation to reduce uncertainties in risk assessment for hazardous substances in foods. The project generalizes the information obtained from experiments to form the basis for developing emerging policy. Project activities include

- developing and evaluating models for identifying toxic hazards associated with food additives;
- conducting studies on the modulating effect of dietary substances on responses to known toxicants;
- conducting pharmacokinetic studies to trace the fate of hazardous substances within the body and the effect of different exposures on distribution; and
- determining dose/effect relationships associated with the incidence and severity of hazardous substances' effects.

Food and Color Additive Petition Review and Policy Development

This project's mission is to ensure that the use of food and color additives is safe by evaluating new petitions and developing and maintaining a data base necessary for evaluation and monitoring. The project also develops policies that direct agency resources to issues of greater concern and anticipate future trends and technological advances. Project activities include

- reviewing technical data submitted for food and color additive petitions, or technical data for affirmation petitions for additives generally recognized as safe;

- conducting inspections to ensure that food and color additives are properly used in manufacturing food;
- examining food products and food contact surfaces for the presence of unapproved or excessive amounts of food additives;
- developing new analytical methodologies to determine the presence of additives in food;
- maintaining and updating a data base on the toxicity and use of previously approved food additives; and
- monitoring research on the toxicity of chemicals likely to become components of additives to ensure that purity specifications for additives are appropriate.

Colors and Cosmetics Technology

This project's mission includes ensuring that all colors used in foods are safe for their intended use. Project activities include

- performing certification analyses on manufactured batches of color additives to enforce FDA chemical specifications;
- developing analytical methods and performing scientific research on colors to identify hazardous ingredients and constituents; and
- conducting sanitary inspections of color-manufacturing establishments to ensure that products are prepared, packed, and held in accordance with FDA regulations and good manufacturing practices, and collecting samples for evaluation.

Postmarket Surveillance and Epidemiology

This project's mission is to strengthen postmarket surveillance activities to enhance consumer protection against new and unforeseen risks with marketed products. Project activities include

- performing postmarket surveillance of the safety of food ingredients, such as sulfites, aspartame, vitamins, and minerals;
- improving methods used to estimate human intake and exposure to foods and food components;
- gathering and evaluating survey and epidemiological data on the relationships between exposure to specific food components and possible adverse reactions;
- performing the biennial Food Label and Packaging Survey;
- performing annual consumer surveys to determine knowledge, attitudes, and buying practices concerning foods; and
- performing consumer surveys addressing specific health concerns.

Technical Assistance

This project's mission includes providing technical assistance to (1) states, in the areas of food safety at the retail level, safety and quality of shellfish, and safety and wholesomeness of domestic milk and milk

products; (2) consumers, industry, and health professionals, to aid in promoting a better awareness and understanding of food issues; and (3) foreign governments, to aid them in carrying out their food responsibilities. Project activities include

- providing national sanitation requirements for food service, food stores, and food vending in the form of model codes; promoting their adoption; and evaluating state programs;
- providing sanitation requirements for producing and processing milk and milk products;
- administering and monitoring the Federal/State Cooperative Interstate Milk Shippers Certification Program and the Dairy Safety Initiative Program;
- conducting on-site evaluations of FDA-accredited milk laboratories triennially;
- promoting sanitation control over all phases of shellfish growing, harvesting, processing, and marketing operations; and
- disseminating information about FDA's food activities to consumers, industry, and health professionals.

Center for Veterinary Medicine Activities

The Center's programs are designed to ensure the safety and efficacy of drugs given to and feeds eaten by animals and the safety of the food produced from animals. The food products regulated under the Center's programs are pet foods and livestock and poultry feeds. In 1988, the retail value of pet foods was about $6.6 billion and the retail value of livestock and poultry feeds was about $20.6 billion.

Animal drug and medicated feed use is extensive. FDA estimates that about 80 percent of the livestock and poultry in the United States is treated with some animal drug or medicated feed. Also, FDA's automated animal drug data system contains information on over 12,000 animal drug products.

The Center's two major projects are (1) Pre-Approval Evaluation of Animal Drugs and Food Additives and (2) Monitoring of Animal Drugs, Feeds, and Devices.

Pre-Approval Evaluation of Animal Drugs and Food Additives

This project's mission is to ensure that (1) new animal drugs and food additives are safe, effective, and properly compounded, formulated, and manufactured; (2) clinical and nonclinical investigations intended to demonstrate the safety or effectiveness of new animal drugs and food additives are conducted in a valid scientific manner; and (3) unapproved

animal drugs for which export is requested comply with FFDCA. Project activities include

- developing guidelines for sponsors of new animal drugs and food additives;
- reviewing Investigational New Animal Drug and Investigational Food Additive Exemptions for adequacy of food safety data, withdrawal periods, and labeling;
- reviewing and evaluating New Animal Drug Applications and Food Additive Petitions for effectiveness, animal safety, environmental impact, labeling, and human food safety;
- reviewing medicated feed applications for formulation accuracy, adequacy of manufacturing practices and labels, and adherence to approved regulations;
- reviewing animal drug export applications to ensure that FFDCA requirements have been met;
- monitoring nonclinical laboratories to determine that they are in compliance with FDA good laboratory practices regulations; and
- monitoring clinical investigators and sponsors to ensure the quality and reliability of test data submitted to FDA.

Monitoring of Animal Drugs, Feeds, and Devices

The project's mission is to ensure that (1) animal drugs, feeds, and medical devices marketed in interstate commerce are safe and effective and are not otherwise adulterated or misbranded; (2) all medicated feeds are properly formulated, manufactured, labeled, and distributed; and (3) harmful residues do not enter the human food supply. Project activities include

- evaluating information submitted on approved new animal drugs and initiating appropriate action to ensure that such products are safe and effective or are removed from the market;
- reviewing advertising, promotional material, and labeling of animal drugs and devices in interstate commerce;
- inspecting manufacturing and distribution facilities to ensure compliance with New Animal Drug Applications, good manufacturing practices, and other FFDCA and regulatory requirements;
- inspecting medicated feed-manufacturing sites;
- collecting and analyzing samples of marketed animal drugs to determine their compliance with FFDCA and removing from the market those that fail to comply;
- collecting and analyzing animal feed samples for adulterants, such as pesticides, heavy metals, naturally occurring toxicants, pathogenic microorganisms, and industrial chemicals;

- inspecting, sampling, and analyzing imported drugs to ensure compliance with FFDCA; and
- coordinating FDA, EPA, USDA, and state activities regarding illegal residues in animal-derived human food.

Office of Regulatory Affairs Activities

The Office of Regulatory Affairs consists of a headquarters staff and FDA field offices. The headquarters staff oversees field office activities. During fiscal year 1989, about 91 percent of the Office's staff was located in FDA field offices. These field offices carry out inspection and enforcement activities relating to all FDA programs, including the food safety and quality programs of the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

Inspection Activities

FDA inspects food establishments for many reasons, including compliance with FFDCA and FDA regulations in the areas of sanitation, ingredient labeling, nutrition labeling, good manufacturing practices, low-acid canned foods, acidified foods, and food standards. The inspections can be comprehensive and cover everything under FDA's jurisdiction or they can be directed at a specific area.

About 53,000 food establishments are subject to FDA inspection. FDA inspected 9,409 food establishments in fiscal year 1986, 8,343 in fiscal year 1987, 7,031 in fiscal year 1988, and 6,368 in fiscal year 1989.

Table 1.1 shows the number of domestic food inspections and samples analyzed by or for FDA for selected fiscal years. (Table 1.2 gives information on FDA's import food inspections.)

Table 1.1: Domestic Food Inspections and Samples Analyzed by or for FDA for Selected Fiscal Years

Dollars in Millions

Fiscal year	Number of inspections: FDA	Number of inspections: State contract	Samples analyzed
1980	16,243	NA	16,440
1985	12,463	11,943	23,010
1988	8,232	7,152	19,965
1989	7,568	7,766	20,098

NA = Not available

Source: FDA

Import Activities

Under FFDCA, FDA is responsible for ensuring that imported FDA-regulated products, such as food, meet the same safety and labeling standards as

domestically produced products. The act also provides that the Secretary of the Treasury shall deliver to HHS, upon request, samples of imported food for examination to ensure that they comply with the act.

FDA field office personnel carry out import inspections at various airports, seaports, and warehouses across the country. Inspections generally consist of two parts: (1) a manual review of all paperwork accompanying products subject to FDA regulation to determine whether physical inspection is warranted and (2) a physical inspection of products suspected of being either adulterated, misbranded, or both. These inspections range from wharf examinations, consisting of a quick, visual examination of products, to collecting samples for laboratory analysis.

In 1988, the value of food-related imports was about $20.6 billion. The two largest categories in dollar terms were fish and fish preparations (about $6.3 billion) and fruits and vegetables (about $5.5 billion).

Table 1.2 shows the number of wharf examinations conducted and samples examined by FDA relating to imported food for fiscal years 1984 through 1989. Wharf examinations may be conducted on products discharged from vessels on the wharves, in pier sheds, or at other locations or they may be conducted on products in trucks or trains at border entry points.

Table 1.2: Wharf Examinations Conducted and Samples Examined by FDA Relating to Imported Food, Fiscal Years 1984-89

Fiscal year	Wharf examinations	Samples examined
1984	26,200	19,150
1985	28,800	20,600
1986	35,650	26,350
1987	33,040	29,890
1988	36,760	32,590
1989	63,006	37,570

Source: FDA

Imported products that fail to meet FFDCA and FDA regulatory requirements are considered to be violative. They are detained at import entry locations and must be exported, destroyed, reconditioned, or relabeled to bring them into compliance with federal laws and regulations. Table 1.3 shows the number and type of import detentions by FDA during fiscal years 1988 and 1989.

Table 1.3: FDA Import Detentions, Fiscal Years 1988-89

	Fiscal year	
Type of detention	**1988**	**1989**
Food sanitation	9,017	8,685
Pesticide and chemical contamination	3,821	5,420
Color/food additives	1,496	1,807
Food economics	4,982	3,594
Total	**19,316**	**19,506**

Source: FDA

Export Activities

FDA does not have a program specifically targeted to the safety of foods that are to be exported. However, FDA does evaluate the status of products that are being exported because they were refused admission to the United States to determine if they comply with the export provisions of FFDCA.

Enforcement Activities

FFDCA and FDA regulations provide FDA with authority for a variety of actions to handle violations of the act and regulations. FDA can issue written warnings to violators, request voluntary recall of violative products, initiate seizures of violative products, seek court-ordered injunctions, and seek criminal prosecutions and penalties. Also, firms or individuals responsible for violative products may take voluntary corrective action, such as voluntarily destroying or removing the products from the market.

Written Warnings

FDA issues two types of written warnings for violative foods—regulatory letters and notices of adverse findings. FDA issues a regulatory letter when it concludes that a violation is serious enough to warrant immediate action, such as seizures, injunctions, or criminal penalties against firms or individuals if corrective action is not taken. FDA issues a notice of adverse findings when it concludes that a violation is not serious enough to warrant immediate action against firms or individuals but is serious enough to warrant some type of written notice. The firms or individuals are requested to provide FDA with written responses, usually within 10 days for regulatory letters and 30 days for notices of adverse findings, detailing actions to correct existing violations and to prevent future violations.

For foods, FDA issued 39 regulatory letters and 607 notices of adverse findings in fiscal year 1988 and 12 letters and 556 notices of adverse findings in fiscal year 1989. For animal feeds, FDA issued 52 regulatory

letters and 201 notices of adverse findings in fiscal year 1988 and 29 letters and 176 notices of adverse findings in fiscal year 1989.

Voluntary Corrections and Recalls

Food-related voluntary corrections totaled 2,472 in fiscal year 1988 and 2,396 in fiscal year 1989. For animal feeds, 106 occurred in fiscal year 1988 and 79 in fiscal year 1989.

Food product recalls totaled 470 in fiscal year 1988 and 570 in fiscal year 1989. There were 50 recalls pertaining to animals for human food use relating to the Center for Veterinary Medicine's activities during fiscal year 1988 and 39 in fiscal year 1989.

Seizures, Injunctions, and Prosecutions

Adulterated or misbranded products not voluntarily destroyed or recalled from the market may be seized by U.S. marshalls on orders obtained by FDA from federal district courts. Persons or firms responsible for violations may be prosecuted in federal courts and if found guilty, may be fined and/or imprisoned. Continued violations may be prohibited by federal court injunctions.

Table 1.4 shows the number of seizures, injunctions, and prosecutions relating to food safety and quality for fiscal years 1988 and 1989.

Table 1.4: Seizures, Injunctions, and Prosecutions Relating to Food Safety and Quality, Fiscal Years 1988-89

	Fiscal year	
Type of action	**1988**	**1989**
Center for Food Safety and Applied Nutrition		
Seizures	137	77
Prosecutions	14	9
Injunctions	3	5
Center for Veterinary Medicine		
Seizures	3	4
Prosecutions	1	1
Injunctions	0	2

Source: FDA

FDA's Relationship to State Inspection Programs

FDA pointed out that with few exceptions, FFDCA does not contain specific preemption language regarding federal versus state regulatory requirements. Therefore, FDA neither wishes for nor is in a position of federal oversight and approval of state programs and state employees. Instead, FDA operates in a cooperative partnership relationship with state agencies. FDA-related state activities, whose value FDA estimated at about $175 million, are scattered among about 400 different state agencies.

State activities and regulatory authorities under state acts vary greatly from state to state. FDA estimated that about 70 percent of the states' FDA-type activities relate to food and about 30 percent relate to other FDA programs.

Four FDA programs—Cooperative Programs, State Contract Program, Voluntary Work Agreement Program, and FDA Commission Program—involve the use of state personnel. Descriptions of these programs follow.

Cooperative Programs

According to FDA, one group of state programs for which FDA may be viewed as having some oversight are the cooperative state programs. In some food and drug areas, state agencies have more direct control of regulatory activities. These areas include milk, shellfish, retail food stores, and food service (restaurants). FDA's role is to provide technical guidance, training, and evaluation of these state programs at the state's request through associations, such as the Interstate Conference on Milk Shipments and the Interstate Shellfish Sanitation Conference. FDA sets standards with the states, evaluates the states against those standards, and rates state officials for their competency, familiarity with, and uniformity in applying those national standards within an individual state. FDA emphasized, however, that it generally is in no position to approve or disapprove a state program.

Through the cooperative programs, FDA, with a small investment of its own resources, promotes and hopes to ensure maintenance of a uniform system of state control over an inventory of about

- 560,000 food service establishments,
- 150,000 retail food stores,
- 1 million food vending locations,
- 126,000 Grade A milk farms,
- 770 milk pasteurization plants,
- 750 shellfish processors,
- 1,100 shellfish shippers, and
- 850 shellfish-growing areas.

State Contract Program

This program is designed to obtain state assistance in inspecting firms that are FDA's responsibility but that would not be covered by FDA employees. The program covers a variety of areas, including food sanitation and medicated animal feeds.

In fiscal year 1989, FDA awarded 113 contracts to 45 states and Puerto Rico at a total cost of about $5.3 million. The program included such projects as investigations of pesticide residues in foods, illegal drug residues in edible animal tissues, and toxins in shellfish.

Voluntary Work Agreement Program

FDA has entered into agreements with state agencies to increase overall consumer protection through more efficient use of federal and state resources. The agreements are intended to minimize overlapping and duplicative coverage of industries regulated by both FDA and the states. The agreements are based on voluntary cooperation; they do not provide federal funds to compensate state agencies for cooperative activities.

FDA Commission Program

FDA Commissions provide authority to 367 state and local officials to help FDA enforce FFDCA. The FDA commissioning system is designed to use the state and local officials to perform specifically designated functions that are subject to federal jurisdiction, such as to conduct examinations, inspections, and investigations. The basic reason for having the FDA Commission is that some states do not have statutory authority to conduct inspections of some kinds of establishments in the FDA Official Establishment Inventory, to review and copy records of interstate shipments, or to collect product samples for FDA.

Funding Levels

FDA's food safety and quality activities are funded through a combination of federal appropriations and reimbursements. Table 1.5 shows the amounts available for FDA's Food and Cosmetics Program and Animal Drugs and Feeds Program and the reimbursable amounts related to foods.

Table 1.5: Amounts Available for FDA's Food and Cosmetics Program and Animal Drugs and Feeds Program for Selected Fiscal Years

Dollars in thousands

	Fiscal year			
	1980	**1985**	**1988**	**1989**
Food and Cosmetics Program[a]	$95,107	$110,541	$126,401	$132,265
Animal Drugs and Feeds Program[a]	19,145	23,427	25,406	26,047
Total	**$114,252**	**$133,968**	**$151,807**	**$158,312**
Total FDA operating appropriation	$320,720	$412,894	$476,054	$517,956
Reimbursements related to foods	$155	$545	$176	$216

[a]Includes funding for some activities not directly related to food safety and quality

Source: FDA

Staffing Levels

Table 1.6 shows the staffing levels for the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, and the staffing levels relating to foods for the Office of Regulatory Affairs and its field offices. The total staffing level decreased about 8 percent from 2,530 in fiscal year 1980 to 2,337 in fiscal year 1989. However, total staffing levels have remained consistent from fiscal year 1985 to fiscal year 1989.

Table 1.6: Staffing Levels for FDA Offices Involved With Food Safety and Quality Activities for Selected Fiscal Years

	Fiscal year			
Organization	**1980**	**1985**	**1988**	**1989**
Center for Food Safety and Applied Nutrition[a]	976	859	826	817
Center for Veterinary Medicine[a]	238	253	244	244
Office of Regulatory Affairs				
Headquarters	94	106	112	114
Field	1,222	1,118	1,151	1,162
Total	**2,530**	**2,336**	**2,333**	**2,337**

[a]Includes staffing for some activities not directly related to food safety and quality

Source: FDA

Coordination With Other Federal Agencies

During fiscal year 1989, FDA had 27 memorandums of understanding (agreements) relating to food safety and quality with other federal agencies, primarily USDA. The agreements vary in scope, detail, and number of agencies involved. For example, some are with one agency and are limited in scope, such as the agreement with USDA's Agricultural Marketing Service involving aflatoxin in peanuts. Other agreements are with several agencies and are broader in scope, such as the agreement between FDA, EPA, and USDA concerning residues of drugs, pesticides, and environmental contaminants in food. The following describes provisions of the main agreements relating to the implementation of the principal food safety and quality legislation and with whom they were made:

- Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Food. This agreement between FDA, EPA, AMS, and USDA's Food Safety and Inspection Service (FSIS) establishes the working relationships for promoting more effective, efficient, and coordinated federal regulatory activities concerning residues of drugs, pesticides, and environmental contaminants that may adulterate food. EPA is to notify FDA and USDA of any pesticide use it encounters that may have resulted in residues that adulterate human food or animal feed. FDA is to

notify EPA of possible misuse of pesticides or chemical substances that may indicate a violation of EPA's laws and to notify USDA of illegal residues of drugs, pesticides, or environmental contaminants in human food or animal feed which indicate that the residues may also be present in meat, poultry, or egg products. USDA is to notify FDA of findings of illegal residues in edible meat, poultry, or egg products and to keep FDA and EPA informed of all FSIS and AMS sampling and testing programs for illegal residues.

- Inspection of Food-Manufacturing Firms. This agreement with FSIS is intended to minimize duplication of inspection effort by exchanging work-planning information and referring violative conditions concerning food manufacturers whose facilities are under the jurisdiction of both FSIS and FDA. FSIS is to contact FDA whenever FSIS inspections disclose that products under FDA's jurisdiction are being handled under unsanitary conditions or are otherwise believed to be adulterated. FDA is to do the same for products under FSIS' jurisdiction. FDA also is to instruct its investigators to (1) attempt to contact any on-site FSIS inspectors on their arrival at a plant, (2) invite the FSIS inspector to participate in the FDA inspection, and (3) report any adverse findings involving meat and poultry products to on-site FSIS inspectors before leaving the plant.
- Recall of Meat and Poultry Products. This agreement with FSIS pertains to meat and poultry products that have been manufactured in an FSIS-inspected establishment and that contain food ingredients that have been recalled by FDA. On learning of a recall situation, FDA is to furnish FSIS with the rationale on which the recall is based and the identity of the USDA-inspected firms known or suspected by FDA to have received the food ingredients being recalled. On receiving information of a recall from FDA, FSIS is to evaluate manufacturing procedures in consultation with FDA to determine the need for the secondary recall of USDA-inspected meat and poultry products.
- Administration of the Egg Products Inspection Act. This agreement with AMS provides that AMS shall have jurisdiction (1) in official and exempted egg products plants; (2) in checking egg producers, packers, and other firms engaged in marketing eggs, including hatcheries, to determine the disposition of restricted eggs; and (3) over imported egg products. FDA shall have jurisdiction over restaurants, institutions, food-manufacturing plants, and other similar establishments that break and serve eggs or use them in their products. In addition, AMS is to notify FDA whenever it believes that shell eggs or egg products have been shipped in commerce in violation of the act to a receiver for which FDA has jurisdiction. FDA is to notify AMS of any unwholesome egg products it encounters.

- Inspecting and Sampling Dry Milk Product Plants. This agreement with AMS establishes procedures for coordinating the two agencies' activities relating to inspecting and sampling dry milk product plants to determine whether products are contaminated with salmonella microorganisms. AMS has two types of voluntary inspection programs for dry milk product plants. Under the Plant Inspection Program, AMS surveys plants for approval every 3 months. Under the Resident Inspection and Grading Program, a plant's processing operation and all finished products are subject to continual AMS inspection. The agreement generally provides that AMS will inform FDA of the plants that are under the two programs and the results of the salmonella tests. FDA will rely on AMS' salmonella surveillance program and generally will not sample for salmonella the dry milk products from the plants operating under AMS' program.
- Inspection and Grading of Food Products. This agreement with AMS pertains to the agencies' inspection and standardization activities for food products, including fruits and vegetables. AMS is to provide FDA a list of the food processing and packaging plants operating under AMS continual or other resident-type inspection/grading contracts and to notify FDA whenever AMS terminates or denies inspection services at a plant because of sanitation or other current good manufacturing practice deficiencies. FDA is to invite the AMS inspector stationed at a plant to accompany the FDA inspector during the FDA inspection. FDA also is to immediately notify the appropriate AMS field office whenever FDA finds objectionable conditions in plants where AMS is conducting inspections and in other plants when FDA believes the information would be valuable to AMS.
- Inspection and Standardization of Grain, Rice, Pulses, and Food Products. This agreement with USDA's Federal Grain Inspection Service (FGIS) pertains to the inspection of facilities that process, hold, and distribute grain, rice, pulses, and similar food products. When FDA is inspecting a facility where an FGIS inspector or licensee is stationed, FDA is to request the FGIS representative to accompany the FDA inspector during the inspection. FGIS is to promptly notify FDA of facilities that are subject to withdrawal or suspension of service, termination of contract, or denial of official FGIS services because of unsanitary conditions or other processing deficiencies. Each agency is to notify the other of serious objectionable conditions found during inspections.
- Inspection of Fishery Products. An FDA memorandum of understanding with the National Marine Fisheries Service (NMFS), Department of Commerce, covers fishery products plants that are under NMFS voluntary

inspection contracts and also subject to FDA inspection. The memorandum provides that NMFS is to apply to plants and products under voluntary NMFS inspection appropriate FDA requirements pertaining to good manufacturing practices, labeling, food additives, tolerances, standards of identity, minimum quality, and fill of container. NMFS is to notify FDA if inspections reveal violations of mandatory FDA requirements, and FDA is to notify NMFS of any official seizure actions taken by FDA regarding fishery products processed or packed in NMFS-inspected plants.

Critical Food Safety and Quality Issues Facing FDA During the 1990s

Both the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine provided information on critical food safety and quality issues of the 1990s. The following issues are among those cited by the Center for Food Safety and Applied Nutrition:

- The safety of foods produced by biotechnology and other novel means.
- Policies and programs for the microbial safety of foods, including the implications of increasing the ease and sensitivity of pathogen detection.
- Policies and programs for monitoring the food supply, including the proper balance of surveillance and inspection activities.
- The agency's role in educating the public about food quality and safety, including the issues of food labeling, nutrition labeling, and dietary advice to high-risk groups.
- The use of appropriate regulatory tools, including the application of food standards and food labeling to include warning labeling.

The Center also set out various groups' roles in meeting future challenges as follows:

- FDA's role includes providing for a network among the various food-related organizations to allow for a broad-based and timely exchange of information on food programs.
- The private sector's and consumers' roles include ensuring that open communication is maintained that allows for a meaningful exchange of information on food safety and quality policy and program issues.
- The executive branch's role includes consultation with executive branch organizations to ensure that proper roles are established and that efforts are effective and not duplicative.
- Congress' role includes granting FDA authority to access records kept by food firms and consideration of additional surveillance authority to augment current inspection authority.

The Center for Veterinary Medicine provided the following list of critical food safety and quality issues of the 1990s:

- Mycotoxin (a toxic substance produced by a fungus) contamination of grains and other feedstuffs and the control procedures used.
- Pesticide and industrial chemical contamination of feeds and feed ingredients.
- Microbiological contamination of feed ingredients and the control procedures used.
- Feed and drug products produced using biotechnology.
- The by-product feed ingredient industry, especially industrial wastes used as feed ingredients.
- Product labeling, particularly pet food labeling, as it affects animal health and product quality.
- Drug and chemical residues in meat, milk, and eggs.
- Drugs and additives used in commercial finfish and shellfish.

Environmental Protection Agency Activities Relating to Pesticide Regulation and Tolerance Levels

The Environmental Protection Agency is responsible for regulating all pesticide products sold or distributed in the United States and for establishing tolerances (maximum legal limits) for pesticide residues in or on food commodities and animal feed.

About 815 million pounds of pesticide-active ingredients—those that destroy or control pests—are used annually in U.S. agriculture. Also, virtually all end-use pesticide products also contain one or more inert ingredients—those that propel, dilute, or stabilize the active ingredients—which may also be toxic and pose a food safety risk. About 300 inert ingredients are accepted for use in pesticide products, of which about 600 are accepted for use in food-use pesticide products.

Major Legislation

EPA's food safety activities are conducted pursuant to two principal laws—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.), and FFDCA, as amended (21 U.S.C. 301 et seq.).

Under FIFRA, EPA is required to register pesticide products, specify the terms and conditions of their use prior to being marketed, and remove unreasonably hazardous pesticides from the marketplace. EPA is responsible for ensuring that when pesticides are used according to directions, they will not present unreasonable risks to human health or the environment. The act requires EPA to take into account the economic, social, and environmental costs and benefits in making decisions.

Under FIFRA amendments in 1972, the Congress mandated that EPA assess the safety of all pesticide products that had been previously registered by federal and state governments. The Congress required that EPA reregister these pesticides using current health and environmental protection criteria because the data bases supporting these older pesticide registrations were incomplete or inadequate by present scientific standards. Further amendments in 1978 and 1988 were aimed at expediting reregistration and improving data availability.

Under FFDCA, EPA is responsible for setting maximum allowed residue levels, or tolerances, for pesticide residues on food commodities and animal feed marketed in the United States. If a pesticide is being considered for use on a food or feed crop, the applicant must petition EPA for a tolerance and submit appropriate data so that EPA can define a safe and realistic tolerance level or grant an exemption from the tolerance requirement. Tolerances apply to imported commodities as well as

domestically produced food commodities and animal feed. The tolerance program's purpose is to ensure that U.S. consumers are not exposed to unsafe pesticide residue levels. Under the act, a food product is adulterated if it contains residues of a pesticide for which a tolerance has not been established or it contains residues exceeding the established tolerance.

EPA also administers the Toxic Substances Control Act (15 U.S.C. 2601 et seq.) under which it controls the manufacturing, processing, distribution, use, and disposal of chemical substances and mixtures, including those that can adulterate food.

Organizational Units and Responsibilities

The Office of Pesticide Programs (OPP), a part of EPA's Office of Pesticides and Toxic Substances, is responsible for the overall management of EPA's pesticide regulatory responsibilities under FIFRA and FFDCA.

OPP has six divisions involved with the safety of pesticides: (1) Registration, (2) Special Review and Reregistration, (3) Health Effects, (4) Environmental Fate and Effects, (5) Biological and Economic Analysis, and (6) Field Operations.

The Registration Division registers new pesticide products and new uses and/or new formulations of currently registered products, establishes tolerances or exemptions from tolerance, and revokes tolerances.

The Special Review and Reregistration Division manages the special review process, the reregistration of active ingredients in pesticide products, and the data call-in process under which EPA requires pesticide producers to provide certain data derived from studies.

The Health Effects Division reviews, evaluates, and validates all data submitted on the toxicological effects on humans and animals and potential exposure to pesticides. The Division develops risk assessments on proposed and existing pesticide uses to support registration, special review, reregistration, and tolerance decisions. This includes assessing potential dietary exposures to pesticides in support of EPA decisions.

The Environmental Fate and Effects Division reviews data on pesticides' effects on biological species (other than humans and domestic animals) and pesticides' fate in the environment. The Division performs risk assessments on pesticide uses and oversees OPP's efforts in the areas of

biotechnology, groundwater protection, pesticide monitoring, quality assurance, pesticide disposal, and endangered species protection.

The Biological and Economic Analysis Division conducts analyses on pesticide use and benefits; acquires, validates, and interprets technical data on pesticide use; and performs economic analyses on the quality and yield impacts of EPA regulatory programs. The Division also develops scientific data on pesticide use patterns in support of exposure assessments and provides analytical laboratory capability by validating residue tolerance methods.

The Field Operations Division communicates OPP's regulatory actions, policies, and programs in the field. This includes interacting with EPA regions, OPP's state regulatory counterparts, the public, pesticide users and other interest groups, USDA, and other external institutions.

Program Activities

Food safety is not a unique program element within OPP. However, OPP's activities and programs—such as registering new pesticides, reregistering existing pesticides, establishing pesticide tolerances, and conducting special reviews of pesticides of concern—contribute to and promote food safety and quality. For example, registration of new pesticide products enhances food safety as newer and safer pesticides are allowed to enter the market and replace older, less scientifically advanced products. Also, OPP's activities relating to pesticide tolerances clearly are related to food safety. And reregistration of pesticide products enables EPA to review pesticide products being used in the United States and ensure that proper action is taken to eliminate unsafe chemicals from the market.

Registering New Pesticides

Under FIFRA, EPA is responsible for registering specified uses of pesticide products on the basis of both safety and benefits. EPA can register a pesticide only if it determines that the pesticide will perform its intended function without causing any unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the pesticide's use.

EPA generally must register a pesticide product before it may be sold or distributed in either intrastate or interstate commerce. Registrations are basically licenses for specified uses of pesticide products. A pesticide product registration sets the terms and conditions of that product's use. EPA requires pesticide registrants to label their products as a primary means to regulate risks to people and the environment. For example, EPA

may require that labels provide precautionary statements that restrict the use of a pesticide to trained and certified applicators.

EPA also permits certain limited uses of unregistered pesticides for experimentation to generate data for supporting registration and addressing emergency pest situations.

In addition, a pesticide produced solely for export is not required to be registered with EPA and may be exported regardless of its U.S. regulatory status, subject to certain labeling, reporting, and notification requirements.

EPA requires health and environmental effects data and information from pesticide producers so it can evaluate the risks and benefits of pesticides and make regulatory judgments about the safety of each pesticide proposed for use. These data relate to such information as the potential for inducing adverse health effects and the quantity and nature of residues likely to occur in food or feed crops.

OPP registered 14 new chemicals for the first time under FIFRA in calendar year 1989. This compared with 11 each in calendar years 1987 and 1988.

Reregistering Existing Pesticides

In 1978, the Congress required EPA to expedite the reregistration process, mandated under the 1972 FIFRA amendments, giving priority to pesticides used on food and other uses which present potentially high exposures. To help expedite reregistration, EPA established the Registration Standards process in 1980. A Registration Standard states EPA's evaluation of existing data and identifies incomplete or additional data requirements that registrants must fulfill to reregister a pesticide product. The process' aim is to reevaluate the active ingredients in pesticide products in accordance with new standards for registration. As of December 1989, EPA had issued 197 Registration Standards under its Reregistration Program.

To obtain data needed to prepare Registration Standards, EPA initiated the data call-in process in 1981. Under this process, EPA sends letters to registrants identifying the testing needs and requires the initiation of such studies. EPA also sets deadlines for completing the studies. By the end of fiscal year 1985, EPA had completed calling in chronic toxicity data for all pesticides applied to food crops.

The 1988 FIFRA amendments mandated a comprehensive data call-in and accelerated reregistration process to be implemented over a 9-year period. This mandate covers about 600 cases (or 1,100 active ingredients) appearing in about 25,000 different pesticide products.

Establishing Pesticide Tolerances

If a pesticide is being considered for use on a food or feed crop, the applicant must petition EPA for a tolerance and submit appropriate data so that EPA can define a safe and realistic tolerance level. These data include information on the pesticide's toxicity (potential to cause adverse health effects), the residues that may remain in or on food or feed, and an analytical method that can detect the chemical and any metabolites of concern in the commodity.

Tolerances are the maximum acceptable levels of pesticide residues that may remain in or on food commodities and animal feed as a result of applying a pesticide. Tolerances are aimed at protecting human health while allowing for the production of an adequate, wholesome, and economical food supply. At the request of FDA or USDA, EPA also sometimes recommends enforcement levels (action levels) for residues occurring in food commodities and animal feed for reasons other than the direct application of a pesticide. For example, EPA can recommend to FDA and USDA an action level for residues occurring in food commodities from a pesticide whose registration has been cancelled by EPA but which persists in the environment.

FDA, USDA, and state enforcement agencies are responsible for enforcing tolerances. USDA has monitoring and enforcement responsibilities for pesticide residues in meat, poultry, and egg products. FDA is responsible for monitoring the rest of the nation's food supply. These agencies test samples of food to determine if the food contains residues for which no tolerance has been set or residues exceeding tolerance levels, rendering the food adulterated. Food commodities with residues in excess of tolerance levels or residues for which no tolerance has been set are subject to seizure.

Conducting Special Reviews of Pesticides of Concern

Whenever data on a registered pesticide raise concern about a health or environmental risk, EPA can conduct a detailed risk/benefit analysis under its special review process. This process allows all interested parties to submit to EPA information concerning the pesticide's risks and benefits. At the conclusion of a special review, EPA may decide to continue, restrict, or cancel some or all uses of the pesticide under consideration.

EPA began conducting special reviews in 1975. As of December 1989, selected special review process accomplishments relating to all types of pesticides, including those that show up as residues in food, are as follows:

- Thirty-six chemicals received special review final determinations.
- Eighteen chemicals were returned to the registration process after a pre-special review determination.
- Registrations for seven chemicals were cancelled before the special review process.
- Registrations for 28 chemicals were voluntarily cancelled as a result of the special review process.
- Fourteen chemicals were in the special review process.

Relationship to State Enforcement Programs

The 1978 FIFRA amendments gave states (including American Samoa, the District of Columbia, Guam, Puerto Rico, Trust Territory of the Pacific Islands, and Virgin Islands) primary enforcement responsibility for pesticide use violations. FIFRA authorizes EPA to enter into cooperative agreements with states and Indian tribes for pesticide enforcement and to train and certify pesticide applicators.

EPA has cooperative agreements with states, territories, and Indian tribes to perform enforcement activities, and it oversees the management of nonfederal enforcement programs. The participating entities conduct use inspections, inspect pesticide-producing establishments, maintain marketplace surveillance, inspect imports, and inspect dealers and users of restricted-use pesticides. They also complete analyses of pesticide samples collected during inspections. In most instances, they develop enforcement cases and issue enforcement actions when violations are detected. In a limited number of instances, they refer cases to EPA for action.

During fiscal year 1989, EPA had enforcement agreements with all states (except Colorado, Nebraska, and Wyoming in terms of private applicators), the District of Columbia, Puerto Rico, 5 territories, and 8 enforcement grants with 14 Indian tribes. In the nonparticipating states, EPA sets FIFRA enforcement policy and conducts compliance monitoring and enforcement programs. In fiscal year 1989, EPA obligated a total of about $8.8 million for pesticide enforcement grants. Table 2.1 shows selected enforcement activity data for states, territories, and Indian tribes operating under enforcement cooperative agreements for fiscal years 1988 through 1990.

Table 2.1: Selected Pesticide Enforcement Activity Data for States, Territories, and Indian Tribes, Fiscal Years 1988-90

Activity	Fiscal year 1988	1989	1990 (est.)
Use inspections	12,639	19,308	18,829
Producer establishment inspections	1,488	1,662	2,509
Marketplace inspections	5,662	8,032	4,035
Import inspections	273	431	475

Source: EPA

Cooperative agreements with states, territories, and Indian tribes to certify and train applicators who use restricted use pesticides are set up under the cooperative program called Pesticides Program Implementation. In fiscal year 1989, EPA obligated a total of about $4.97 million for this program, including $3.98 million for the program's grant portion.

Funding Levels

OPP activities are funded primarily by federal appropriations. Since implementation of the 1988 FIFRA amendments, which established a separate reregistration fee system, the Reregistration and Expedited Processing Revolving Fund (FIFRA Revolving Fund) has also provided resources. In fiscal year 1989, about 90 percent of OPP's $54.7 million funds (excluding funds for disposal of suspended or cancelled pesticides) were federal funds, with the remaining 10 percent charged to revolving funds—$5.2 million from the FIFRA Revolving Fund and $1 million from the Tolerance Revolving Fund.

Table 2.2 shows OPP's actual obligations for fiscal years 1980 through 1989, excluding funds for disposal of suspended or cancelled pesticides. For comparison purposes, special funding of $7.4 million for fiscal year 1988 and $41.3 million for fiscal year 1989 for disposal of suspended and cancelled pesticides was not included in the table since the funds were for a special purpose and were available only for fiscal years 1988 and 1989. The Generic Chemical Review Program includes funding for EPA's reregistration and special review activities.

Table 2.2: EPA/OPP Obligations, Fiscal Years 1980-89

Dollars in Millions

	Fiscal year									
Program	**1980**	**1981**	**1982**	**1983**	**1984**	**1985**	**1986**	**1987**	**1988**	**1989**
Generic Chemical Review	$28.2	$28.1	$22.1	$20.0	$20.4	$24.2	$23.5	$25.1	$27.4	$33.1[a]
Registration	6.9	8.4	8.2	7.8	9.9	14.9	12.7	12.6	11.8	16.2
Special Registration	2.2	2.5	1.9	2.6	2.7	2.1	1.9	1.9	2.0	[b]
Tolerances	2.2	2.1	2.1	2.1	2.5	3.2	2.7	2.6	2.9	[b]
Laboratory Support	•	•	•	•	.1	.3	.2	.3	.2	.4
Pesticide Program Implementation[c]	•	•	•	•	•	•	•	•	4.6	5.0
Total	**$39.4**	**$41.2**	**$34.4**	**$32.4**	**$35.6**	**$44.6**	**$41.0**	**$42.5**	**$48.9**	**$54.7**

Note: Columns may not add to totals because of rounding

[a]Includes $5.2 million charged to the FIFRA Revolving Fund

[b]Beginning in fiscal year 1989, resources for Registration, Special Registration, and Tolerances were merged into the Registration program element

[c]Beginning in fiscal year 1988, the Pesticide Program Implementation program element was transferred from EPA's Office of Compliance Monitoring to OPP

Source: EPA

Staffing Levels

During fiscal year 1989, OPP maintained a headquarters staff in Arlington, Virginia, and supported certification and training staff in EPA regions. In fiscal year 1989, about 97 percent (604) of OPP's total full-time equivalent staffing of 624 were in headquarters, with the remaining 3 percent allocated to regional offices. Table 2.3 shows OPP's full-time equivalent staffing levels for fiscal years 1980 through 1989.

Table 2.3: EPA/OPP Full-Time Equivalent Staffing Levels, Fiscal Years 1980-89

	Fiscal year									
Program	**1980**	**1981**	**1982**	**1983**	**1984**	**1985**	**1986**	**1987**	**1988**	**1989**
Generic Chemical Review	354	304	221	193	208	250	272	272	307	338[a]
Registration	243	231	214	193	220	218	195	195	166	264
Special Registration	80	66	51	63	61	45	41	39	43	[b]
Tolerances	78	76	82	76	66	78	72	69	71	[b]
Pesticide Program Implementation	•	•	•	•	•	•	•	•	15	22
Total	**755**	**677**	**568**	**525**	**555**	**591**	**580**	**575**	**602**	**624**

[a]Includes 31 full-time equivalent staffing funded by the FIFRA Revolving Fund

[b]Beginning in fiscal year 1989, resources for Registration, Special Registration, and Tolerances were merged into the Registration program element

[c]Beginning in fiscal year 1988, the Pesticide Program Implementation program element was transferred from EPA's Office of Compliance Monitoring to OPP

Source: EPA

Coordination With Other Federal Agencies

To coordinate its food safety activities with other federal agencies, EPA had four written memorandums of understanding, as follows, with FDA and/or USDA:

- Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Food. This agreement between EPA, FDA, and USDA is described in part 1.
- Responsibilities Under FFDCA and FIFRA. This agreement with FDA provides for coordination of activities pertaining to pesticide chemical products subject to the requirements of both FFDCA and FIFRA. The agreement specifies the types of petitions or applications that will be processed by each agency and provides for notifying product manufacturers of which agency has primary jurisdiction over the product.
- Pesticide Benefit/Risk Assessments. This agreement between EPA and USDA establishes procedures for coordinating the two agencies' activities relating to evaluating the benefits and risks of pesticides subject to regulatory decisions under FIFRA. The agreement implements a FIFRA provision that requires EPA to notify USDA of EPA regulatory proposals that affect agriculture. USDA may comment on the proposals and related analyses of agricultural impact before the proposals are finalized.
- Training Pesticide Applicators. This agreement with USDA's Extension Service provides for coordination in providing training to restricted-use pesticide applicators through State Cooperative Extension Services' programs.

Critical Food Safety and Quality Issues Facing EPA During the 1990s

According to EPA, most of the critical pesticide food safety and quality issues of the 1990s are addressed in the proposed changes in FIFRA and FFDCA contained in President Bush's October 1989 Food Safety Plan. The Plan, which was developed with the assistance of EPA, USDA, and HHS, is intended to improve the federal government's ability to protect American consumers and the environment from potential dangers posed by the use of pesticide chemicals. The Plan's key points are discussed below.

Streamlined FIFRA Cancellation Procedures

Under FIFRA, EPA can cancel a pesticide registration if it determines that the pesticide's use causes unreasonable adverse effects to human health or the environment. However, cancellation currently can take 4 to 8 years to complete, because of extensive information gathering by EPA and provisions in the law for challenging EPA decisions.

Under the President's Plan, the cancellation process would be shortened by about half by eliminating the formal adjudicatory hearing and substituting a notice and comment procedure. An informal hearing may be held during the comment period, and EPA's final decision could be challenged in federal courts.

Improved Suspension Authority Under FIFRA

Because the pesticide cancellation process takes a long time, FIFRA allows EPA to suspend pesticides during the cancellation process under certain circumstances. According to EPA, the current FIFRA suspension standards have proven difficult to implement and have prevented EPA from removing pesticides from the market in a timely manner when substantial safety questions exist.

The President's Plan proposes redefining the standard for "imminent hazard" suspensions to provide EPA greater flexibility in using its suspension authority. The Plan provides that when the risk associated with a pesticide is high, EPA may order a suspension without considering the pesticide's economic benefits and without a hearing. When the risk may be lower or there is greater uncertainty, EPA may order a suspension after some consideration of the impact on food prices and availability.

Periodic Reregistration Review

The 1988 FIFRA amendments require that pesticides first registered before 1984 undergo accelerated reregistration to bring the data bases supporting their use up to current scientific standards. Accelerated

reregistration is underway, but it covers only those chemicals first registered prior to 1984, and it constitutes only a one-time catch-up to current standards for those pesticides. According to EPA, once the process is completed and time passes, EPA could find itself in a situation once again in which updated scientific data and current reviews are needed.

The President's Plan establishes the principle of an ongoing data-generation and review process for all pesticides, regardless of when they were first registered. Pesticide registrants would be on notice that they will be required to supply EPA with data on a predictable schedule, allowing EPA to determine whether pesticides meet up-to-date standards for registration. The new process is intended to avoid any future need for massive catch-up reregistration efforts while affording the public assurance that the data bases supporting pesticide registrations are being kept current with evolving scientific standards.

Enhanced Enforcement

According to EPA, the current FIFRA is one of the weakest environmental protection statutes in terms of the penalties that can be assessed for significant violations. The maximum civil fine is $5,000 per violation and applies only to persons who sell, distribute, or commercially use pesticides. Other persons who violate FIFRA may be assessed a civil penalty of up to $1,000. In addition, no major changes have been made in the dollar amount of civil fines since 1972—18 years ago—and the statute's criminal violations are considered misdemeanors, regardless of the seriousness of the crime.

EPA stated that current record-keeping and information-gathering authority is also limited. And inspection authority is limited to places where pesticides are held for sale or distribution or places where any suspended or cancelled pesticides are held. This leaves EPA without specific authority to inspect certain persons who are subject to existing requirements under FIFRA.

The President's Plan proposes to bring FIFRA in line with other major environmental statutes. Penalties would be increased for persons who sell, distribute, and commercially use pesticides in violation of the law to a maximum of $25,000 per day per violation. Criminal violations would be raised from misdemeanors to felonies. Also, the proposal would extend the authority to require records to most persons involved in selling or distributing pesticides, applying pesticides for hire, applying restricted-use pesticides, and pesticide-testing facilities. The inspection

authority would also be expanded to testing facilities, persons who commercially apply pesticides, and any place where there is reason to believe FIFRA has been or is being violated.

Compatibility of Pesticide Tolerances

According to EPA, current law has inconsistent provisions relating to food tolerances. Section 408 of FFDCA requires that EPA give appropriate consideration to the need for producing an adequate, wholesome, and economical food supply. FIFRA also directs EPA to balance the risks and benefits of a pesticide's use. However, the Delaney clause of Section 409 of FFDCA, which applies to processed food products, states that no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. If a strict, literal interpretation is given to this clause, it bars EPA from setting a food additive regulation for certain foods which may be processed if there is any evidence of a cancer risk in high-dose animal studies, no matter how small the risk or how large the benefits.

The President's Plan proposes to replace the Delaney clause with a consistent negligible risk standard for all pesticide tolerances posing a carcinogenic risk on both raw and processed foods.

Uniform Tolerances

Under current law, states may set tolerances for pesticide residues in food that are lower than those established by EPA. According to EPA, this situation creates the potential for considerable consumer confusion and substantial disruption of interstate commerce in food products. Inconsistent tolerances could also complicate international trade in raw agricultural commodities and processed foods.

The President's Plan proposes that national uniformity be established by statute for tolerances that are set as a result of EPA's ongoing reregistration efforts and for new pesticides that are reviewed under the revised standards described in the Plan. States would still be able to obtain waivers and establish their own tolerances if special local circumstances exist.

Consultation Within the Federal Government

Current consultation between EPA, HHS, and USDA primarily occurs in the form of written comment during the cancellation process. For example, FIFRA requires EPA to provide USDA an opportunity to comment on proposed notices of intent to cancel a pesticide's registration, and EPA

addresses any USDA comments when EPA issues a final notice of intent to cancel.

The President's Plan would require appropriate consultation between EPA, HHS, and USDA before issuing cancellation and suspension orders and at such other times as they may agree to.

Food Safety and Inspection Service Activities Relating to Meat and Poultry Safety and Quality

USDA's Food Safety and Inspection Service administers a comprehensive system of inspection laws to ensure that meat and poultry products moving in interstate and foreign commerce for use in our food supply are safe, wholesome, and correctly marked, labeled, and packaged.

Major Legislation

FSIS carries out its meat and poultry inspection responsibilities under the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act, as amended (21 U.S.C. 451 et seq.).

The first major amendment to the Federal Meat Inspection Act—the Wholesome Meat Act—was passed in 1967. It established the federal-state cooperative program under which USDA helps fund state inspection programs. It also required state inspection programs to be "at least equal to" the federal program and strengthened the regulation of imported meat. The Wholesome Poultry Products Act of 1968 extended the same provisions to poultry inspection.

In 1986, the Congress enacted discretionary inspection authority permitting FSIS to vary the type of inspection in processing plants depending on the product, the plant's compliance history, and the commitment of plant management to control its operation. Discretionary inspection authority expires in 1992 unless extended by the Congress.

Another act affecting FSIS activities is the Talmadge-Aiken Act of 1962 (7 U.S.C. 450 et seq.). The act established cooperative agreements permitting state employees to carry out inspection in meat and poultry slaughtering and processing plants. These plants are considered to be "federally inspected" and thus may sell their products in interstate commerce.

Organizational Units and Responsibilities

The four major FSIS organizational units that are directly involved with inspection and supportive activities are Inspection Operations, Regulatory Programs, International Programs, and Science and Technology. Their responsibilities are described below.

Inspection Operations

The Inspection Operations unit is responsible for inspecting and monitoring operations in about 6,720 meat and poultry plants throughout the United States and 220 official import establishments to ensure that consumers receive safe, wholesome, and accurately labeled products.

FSIS inspection activities are carried out by a network of 5 regional offices, 26 area offices, and about 200 inspection circuits. Each region is managed by a regional director, who reports to the Assistant Deputy Administrator of Regional Operations. Each of the five or six area offices in each region is managed by an area supervisor, who reports to the regional director. Within each area are several inspection circuits, each managed by a circuit supervisor. Circuit supervisors oversee the inspectors-in-charge of the plants within their circuits.

Regulatory Programs

The Regulatory Programs unit is responsible for managing FSIS' label approval and food ingredient assessment activities, investigating statutory violations, initiating appropriate sanctions, and conducting oversight reviews over agency programs and operations.

International Programs

The International Programs unit is responsible for ensuring that imported meat and poultry products are produced under the control of inspection systems that are equivalent to the U.S. system and that the products are wholesome and correctly labeled. It also supports U.S. exports through technical discussions of foreign inspection requirements, dissemination of export information, and certification that exported products meet U.S. and foreign requirements.

Science and Technology

The Science and Technology unit is responsible for providing the scientific services and technical support necessary to advance meat and poultry inspection beyond detection and toward the prevention of foodborne hazards while relying heavily on risk assessment and quality control. Its support services are designed to assure product safety from disease, harmful chemicals, toxins, and food-poisoning microorganisms, as well as to prevent economic fraud and unsanitary preparation.

The Science and Technology unit maintains laboratories in Athens, Georgia; Alameda, California; and St. Louis, Missouri, to provide analytical support for FSIS activities. It augments the analytical capacity of these laboratories by contracting with nonfederal laboratories.

Program Activities

FSIS' major activities, which are described below, range from setting and reviewing compliance with plant sanitation standards to monitoring state inspection programs and reinspecting imported meat and poultry products.

About 7,800 federal inspectors, including many veterinarians, carry out federal inspection laws in meat and poultry slaughtering and processing plants and at official import inspection facilities. The in-plant inspection work force consists of about 6,050 food inspectors, 180 food technologists, and 1,050 veterinarians.

Plant Sanitation

Before a plant can begin operating as a federally inspected establishment, FSIS must approve its plans for facilities, equipment, and procedures to make sure the operation will be sanitary. Facilities and equipment must be easy to clean and keep clean. Each plant's floor plan, water supply, waste disposal systems, and lighting must be approved. Once a plant begins operating, inspectors monitor the facilities and equipment for sanitation. If, at any time, equipment is not properly cleaned or an unsanitary condition is discovered, the operations are stopped until the problem is corrected. During fiscal year 1989, FSIS reviewed 3,851 blueprints of meat and poultry plants and 2,864 drawings of equipment.

Inspection of Slaughtering Plants

FSIS inspects all animals before they enter an establishment to be slaughtered and carcasses after slaughter. Before slaughter, FSIS veterinarians look for symptoms of disease and other abnormal conditions. After slaughter, inspectors examine each carcass and the internal organs for symptoms of disease or contamination that would make all or part of them unfit for human consumption. Veterinarians supervise the inspectors' work to ensure uniformity in the inspection process and to provide expertise in detecting diseases.

Inspection of Processing Plants

Much of the meat and poultry slaughtered in the United States finds its way into products like frozen dinners, ham, hot dogs, pot pies, sausages, and soups. Before a product can be marketed, FSIS reviews the processing procedures and product recipes to ensure that the products will be safe. Labels are checked for truthfulness and conformance with labeling laws and regulations. The plant inspector monitors the processing operations to make sure the plant adheres to the approved procedures and labels.

Inspection in meat- and poultry-processing plants differs from inspection in slaughtering plants. For example, animals cannot be slaughtered unless an inspector is present, while processing plants are not subject to

continuous inspection. Also, at processing plants, inspectors do not visually examine all items. Instead, they monitor the plant's operation, making use of statistical sampling and laboratory testing. Reasons for this difference are that the meat and poultry have already been inspected by FSIS at slaughtering plants and that many companies use quality control systems.

Residue Testing

Inspection includes checking, on a sample basis, for drug and chemical residues in slaughtered animal tissue. Residues can result from the improper use of pesticides, herbicides, animal drugs, and medicated feeds, as well as from industrial accidents that contaminate animal feeds or the environment where food animals are raised.

Laboratory Samples Analyzed

FSIS performs a large number and a variety of laboratory analyses on meat and poultry products. Table 3.1 contains data on the type and number of laboratory samples analyzed by FSIS for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990.

Table 3.1: Laboratory Samples Analyzed by FSIS, Fiscal Years 1988-90

	Fiscal year		
Sample type	**1988**	**1989**	**1990 (est.)**
Food chemistry	70,021	62,435	62,000
Food microbiology	37,410	36,908	37,000
Chemical residues	102,714	185,163	185,000
Antibiotic residues	223,210	255,851	256,000
Pathology	11,160	11,017	11,000
Serology	3,928	1,630	1,600
Additives/nonfoods	12,007	10,907	10,900
Radiation	3,184	139	•
Total	**463,634**	**564,050**	**563,500**

Source: FSIS

Product Labels

FSIS is responsible for approving formulas and labels of meat products containing over 3 percent fresh meat and poultry products containing 2 percent or more cooked poultry before the products are marketed. During fiscal year 1989, FSIS reviewed a total of 137,687 meat and poultry product labels. Of the total, 25,605 product labels were not approved.

Enforcement

Inspection and, where appropriate, condemnation of adulterated or mislabeled products are the most important ways in which FSIS encourages compliance with laws and regulations. However, the agency can take other actions if they are necessary to prevent adulterated or misbranded products from reaching consumers. These actions include temporarily halting inspection (and thus production) until serious problems are corrected, stopping product distribution, persuading companies to recall violative products, and seeking court-ordered product seizures when necessary.

Monitoring State Inspection Programs

Under the federal-state cooperative inspection program, FSIS monitors state inspection programs, which inspect meat and poultry products that will be sold only within the state in which they are produced. The purpose is to ensure that states apply inspection standards that are at least equal to those of the federal program. About half the states conduct their own meat and poultry inspection programs, and about 5,700 plants are inspected by state programs.

The Federal Meat Inspection Act and the Poultry Products Inspection Act require state inspection programs to be "at least equal to" the federal inspection program and authorize federal reimbursement of up to 50 percent of a state's inspection costs. If states choose to end their state inspection programs or cannot maintain the "at least equal to" standard, FSIS must assume responsibility for inspection. FSIS provided about $36.5 million in grants to 28 states for fiscal year 1989.

Imported Products

FSIS is also responsible for ensuring that imported meat and poultry meet the same standards as domestic products. For a country to be eligible to export meat and poultry to the United States, it must impose inspection requirements "at least equal to" those enforced in the United States. FSIS evaluates a country's total inspection program to determine eligibility, and FSIS officials regularly review the way the systems are operated in eligible foreign countries to ensure that the requirements continue to be enforced. In addition, FSIS reinspects imported meat and poultry products, on a sampling basis, when they enter the United States. As of December 31, 1989, 1,431 plants in 34 countries were certified to export meat or poultry to the United States.

Funding Levels

FSIS activities are funded by federal appropriations, reimbursements, and trust funds. Of the $457.2 million in total funds available to FSIS in

fiscal year 1989, about $405 million (89 percent) were federal funds, about $51 million (11 percent) were reimbursements (nonfederal funds), and less than 1 percent were trust funds. Table 3.2 shows FSIS' actual fiscal year 1988 and 1989 obligations and funds available and the estimated amounts for fiscal year 1990.

Table 3.2: Funds Available to FSIS, Fiscal Years 1988-90

Dollars in thousands

	Obligations for fiscal year		
Program area	**1988**	**1989**	**1990 (est.)**
Slaughter inspection	$250,810	$263,007	$269,070
Processing inspection	119,080	122,559	125,842
Import export inspection	11,277	11,140	11,597
Laboratory services	24,119	23,860	27,296
Grants to states	35,425	36,480	36,574
Total obligations	440,711	457,046	470,379
Unobligated balance lapsing	156	126	•
Total funds available	**$440,868**	**$457,172**	**$470,379**

Note: Columns may not add to totals because of rounding.

Source: FSIS

Staffing Levels

During fiscal year 1989, FSIS maintained a central office in Washington, D.C., 5 regional offices, 26 area offices, and a nationwide network of inspectors in about 7,000 establishments in the 50 states, American Samoa, Guam, Puerto Rico, and the Virgin Islands. As of September 30, 1989, FSIS' staff totaled 8,942 permanent full-time employees and 810 other employees. Of these, 701 permanent full-time employees (8 percent) and 74 other employees were located in the central offices, and 460 permanent full-time employees (5 percent) and 9 other employees were in area and regional offices. The balance of 7,781 permanent full-time employees (87 percent) and 727 other employees was in field locations.

Table 3.3 shows the actual staff years for fiscal years 1988 and 1989 and the estimated staff years for fiscal year 1990 for FSIS' program areas. (The total staff years amounted to about 10,400 for each fiscal year.)

Table 3.3: FSIS Staff Years by Program Area, Fiscal Years 1988-90

Program area	Staff years for fiscal year 1988	1989	1990 (est.)
Slaughter inspection	6,969	7 004	7 042
Processing inspection	2,847	2,791	2,805
Import-export inspection	230	231	232
Laboratory services	384	373	376
Grants to states	•	•	•
Total	**10,430**	**10,399**	**10,455**

Source FSIS

Table 3.4 contains data on FSIS staffing, funding, and inspection activities for fiscal years 1980 through 1989. During this period, FSIS' obligations increased from $311.4 million in fiscal year 1980 to $457 million in fiscal year 1989. However, in constant 1989 dollars, FSIS actually used about 3 percent fewer funds in fiscal year 1989 than in 1980. Moreover, its staff years decreased by about 6 percent—from 11,084 in fiscal year 1980 to 10,399 in fiscal year 1989. During this period of less staff and funds in constant dollars, FSIS' activities increased considerably.

Table 3.4: FSIS Resources and Inspection Activities, Fiscal Years 1980-89

Resources/Activity	Fiscal year 1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Obligations (millions)	$311 4	$330 9	$351 2	$362 3	$375 8	$405 1	$398 0	$416 4	$440 7	$457 0
Staff years	11,084	10,705	10 511	10,490	10 486	10,672	10 259	10,323	10 430	10,399
Establishments inspected	7,061	7,155	7 470	7,449	7,500	7 433	7 415	7,272	7 122	6,943
Pounds inspected (millions)										
Slaughter										
Meat	35,479	36,963	35,873	35,738	36,654	36,193	37,042	36 300	36,885	35,351
Poultry	19,444	20,305	20,575	21,179	21 546	22,980	24 273	25,700	28,213	29,581
Processing										
Meat	70,110	68,695	68,323	66,588	70,327	66,467	66 605	67,158	71,943	74 100
Poultry	34,614	37 217	39 521	45,718	49,535	53,101	60 471	68 500	78,500	80,850
Total	**159,647**	**163,180**	**164,292**	**169,223**	**178,062**	**178,741**	**188,391**	**197,658**	**215,541**	**219,882**
Samples analyzed	200,140	291,822	200 449	212,229	240 918	295 959	331 518	393,376	463,634	564,050
Compliance reviews										
Number	41,715	44 283	42,403	39 909	36,561	51,957	53 118	42,111	56,288	60,366
Recalls (detained meat)	14	7	7	7	6	9	23	13	11	8
Labels (thousands)										
Approved	90	101	111	100	114	115	129	159	155	112
Not approved	15	17	10	15	16	19	19	21	28	26

Source FSIS

Table 3.4 shows that, while the amounts of slaughtered and processed meat inspected remained about the same or increased slightly from fiscal year 1980 to fiscal year 1989, other FSIS food safety and quality inspection activities increased considerably. Examples of such increases follow:

- Pounds of processed poultry inspected increased about 134 percent, from 34.6 billion pounds to 80.9 billion pounds.
- Pounds of slaughtered poultry inspected increased about 52 percent, from 19.4 billion pounds to 29.6 billion pounds.
- Samples analyzed increased about 182 percent, from 200,140 to 564,050.
- Labels reviewed increased about 31 percent, from about 105,000 to about 138,000.
- Compliance reviews increased about 45 percent, from 41,715 to 60,366.

Coordination With Other Federal Agencies

To coordinate its food safety and quality activities with other federal agencies, FSIS has a total of six written memorandums of understanding with EPA, FDA, and, or two USDA agencies—Animal and Plant Health Inspection Service (APHIS) and Agricultural Research Service (ARS). Some of the agreements, such as the one between EPA, FDA, and USDA to coordinate federal regulatory activities relating to drug, pesticide, and environmental contaminant residues in foods (see part 1), are quite extensive and involve many different matters. The following briefly describes some provisions of the other five agreements and with whom they were made:

- Inspection of Food Manufacturing Firms. This agreement with FDA, which was discussed in more detail in part 1, is intended to minimize duplication of inspectional effort by exchanging work-planning information and referring violative conditions concerning food manufacturers whose facilities are under the jurisdiction of both agencies.
- Recall of Meat and Poultry Products. This agreement with FDA, which was also discussed in more detail in part 1, pertains to meat and poultry products that have been manufactured in an FSIS-inspected establishment and that contain food ingredients that have been recalled by FDA.
- Surveillance for Animal Diseases in Food. This agreement with APHIS involves surveillance, testing, investigation, and trace backs to points of origin of diseased animals. FSIS agrees to report to APHIS when carcasses of slaughtered food animals are found to contain significant violative residues resulting from chemicals, pesticides, or adulteration. APHIS agrees to make field investigations of outbreaks of diseases that affect animal health and to advise FSIS of the investigation results.

- Exchange of Information Regarding Animal Samples for the Residue Avoidance Program. This agreement with ARS relates to planning, budgeting, and managing studies on chemical residues in meat. ARS agrees to collect feed, water, medication, animal tissue, and other samples. FSIS agrees to conduct chemical and microbiological analysis on samples at FSIS laboratories.
- Current Research Information System. This agreement with ARS involves research on meat and poultry products done by ARS for FSIS. FSIS agrees to provide ARS, by December 1 of each year, a prioritized list of its specific research needs. ARS agrees to carry out research directed to meeting FSIS' needs within agency budgetary and resource constraints.

Critical Food Safety and Quality Issues Facing FSIS During the 1990s

According to FSIS, three critical issues will face the agency during the 1990s. The greatest will be foodborne pathogens—bacteria and viruses capable of causing human disease. The second is chemical residues, including drugs, pesticides, and environmental contaminants. The third is the modernization of meat and poultry inspection.

Several dozen foodborne bacteria and viruses are considered pathogens. Some of these organisms have been known for a long time; however, new organisms have emerged about which little is known. An example is Listeria monocytogenes, which can be fatal to people with compromised immune systems. While this bacterium has been found in meat and poultry for several years, only recently has a confirmed case of the disease been traced to such a product.

FSIS believes that the United States needs a strong food safety research program to uncover more information about emerging pathogens and to find better ways to control all pathogens. It believes that, as part of this research, rapid tests are needed to determine the presence of the organisms in food.

To help address the pathogen problem, FSIS has increased its sampling for microbiological contaminants almost fourfold during the last 8 years. In fiscal year 1989, the agency analyzed about 37,000 samples for microbiological contaminants.

Regarding chemical residues, FSIS initiated the National Residue Program more than 20 years ago to detect chemical residues in meat and poultry. The program monitors meat and poultry with statistical random sampling. Each year, FSIS conducts more than 1.5 million analyses for chemical and drug residues, testing for 100 to 150 different compounds. The

sampling ensures a 95-percent confidence of detecting a residue if it occurs in 1 percent or more of an animal species, nationwide. FSIS stated that less than 1 percent of all these tests shows illegal chemical residues, meaning the U.S. meat and poultry supply is in good shape regarding chemical contaminants. However, FSIS believes that more research, including development of additional rapid tests for chemical residue detection, is needed.

Regarding modernization of meat and poultry inspection, FSIS believes that this is a necessity. To date, the United States has led the rest of the world in modern inspection technology and needs to continue to do so. The Committee on Meat Hygiene of the Codex Alimentarius Commission—the international organization that represents countries in setting food standards—will be looking at modern U.S. technologies, such as the Streamlined Inspection System for Cattle, as well as those from other countries. FSIS believes that by modernizing inspection and mandating new technologies, it can ensure that the U.S. meat and poultry supply remains the safest in the world, as well as one of the most thoroughly inspected foods in the world.

Agricultural Marketing Service Activities Relating to Safety and Quality of Egg, Dairy, Fruit, Vegetable, Meat, and Poultry Products

USDA's Agricultural Marketing Service carries out a wide array of programs to facilitate the marketing of agricultural products pursuant to more than 30 statutes. AMS' food safety and quality activities, which are at the core of the agency's mission, are conducted pursuant to the five laws discussed below.

Major Legislation

The Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.), (1) requires continual USDA inspection of all egg products- processing plants, (2) requires mandatory quarterly inspections of shell egg handlers who pack eggs for consumer sales, (3) restricts certain types of shell eggs (e.g., leaking, cracked, or dirty eggs) from moving into consumer channels, and (4) prohibits state or local governments from imposing standards differing from official USDA standards for grade and size for eggs moving in interstate commerce.

The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.), authorizes the Secretary of Agriculture to provide services upon request to inspect, certify, and identify the class, quality, quantity, and condition of agricultural products when shipped or received in interstate commerce. The act also authorizes the Secretary to develop and improve standards of quality, quantity, condition, grade, and packaging, and to recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices. Domestic and international standards are developed and maintained for use in the grading and inspection of dairy products, fruits and vegetables, livestock, meat, poultry, rabbits, and shell eggs.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), authorizes the establishment of marketing orders and agreements to regulate the quality, quantity, or container or pack requirements for fruits, vegetables, and certain specialty crops and to regulate the minimum prices that handlers pay to producers of milk and dairy products. The act also requires the regulation of certain of these commodities imported into the United States whenever domestic shipments of the commodities are subject to quality regulations under a marketing order.

The Export Apple and Pear Act, as amended (7 U.S.C. 581 et seq.), and the Export Grape and Plum Act, as amended (7 U.S.C. 591 et seq.), prohibit the shipment of the specified fruits to any foreign destination in packages that are not accompanied by a certificate of quality issued under the Secretary of Agriculture's authority.

Organizational Units and Responsibilities

AMS is organized along commodity lines. Five organizational units are directly involved with food safety and/or quality activities. These are the (1) Poultry Division, (2) Livestock and Seed Division, (3) Fruit and Vegetable Division, (4) Dairy Division, and (5) Commodities Scientific Support Division.

The agency's only food safety regulatory responsibilities are in the egg products and shell egg surveillance programs. The other AMS programs discussed below are focused primarily on food quality, such as establishing standards of quality and condition and grading the quality of dairy, egg, fruit, meat, poultry, and vegetable products.

Program Activities

AMS' food safety and quality activities are conducted through the following programs:

- Egg Products Inspection and Shell Egg Surveillance.
- Commodity Standardization.
- Commodity Inspection and Grading.
- Laboratory Testing.
- Governmentwide Food Quality Assurance.

Egg Products Inspection and Shell Egg Surveillance Programs

The Egg Products Inspection Act is intended to ensure that consumers receive wholesome, unadulterated, and truthfully labeled egg products and to restrict the use of certain types of shell eggs. AMS' Poultry Division administers the Egg Products Inspection and Shell Egg Surveillance Programs.

The act requires continual USDA inspection of all egg product-processing plants involved in intrastate, interstate, and foreign commerce. In 1989, 83 egg products-processing plants were subject to continual USDA inspection, and all were being inspected. Poultry Division inspectors are responsible for inspecting the facilities, equipment, and methods of processing; as well as the products. The facilities and equipment are inspected for cleanliness and the ability to perform the intended functions. Controlling the type of egg broken is a key function of the inspection system.

Egg products are inspected in three forms: liquid, frozen, and dried. Further processed products, such as noodles and custards, which contain egg products but have not been considered as products of the egg food industry, are exempt and therefore not subject to inspection.

The inspection methods involve visual inspection and laboratory tests. Sensory examination of the product is supported by laboratory analyses made by the Commodities Scientific Support Division. Food chemistry, microbiology, and chemical residue tests are performed for various industrial and environmental chemicals, trace elements, drug residues, and similar contaminants.

The act also requires mandatory quarterly inspections of shell egg handlers and restricts certain types of shell eggs from moving into consumer channels to prevent their use as human food. Restricted eggs include checked eggs (those with cracked shells that are not leaking) and dirty eggs, which may be sent only to official USDA-inspected processing plants for proper handling and processing; incubator rejects (infertile or unhatchable eggs); leakers (cracked eggs with contents leaking); and inedible and loss (unfit for human consumption) eggs. Inedible eggs and egg products must be denatured and destroyed or otherwise handled to preclude their use as human food.

In 1989, about 1,500 shell egg-packing plants and 500 hatcheries were subject to, and received, quarterly inspections by USDA or cooperating state agencies. Through cooperative agreements with states, the Poultry Division uses state inspection personnel to make unannounced quarterly shell egg surveillance visits to shell egg-packing establishments. AMS has cooperative agreements with all 50 states, Puerto Rico, and the Virgin Islands. During fiscal year 1989, visits were made by nonfederal agencies in all but five states or other jurisdictions. In these locations, federal employees performed the work. AMS provides federal oversight for the state programs and reimburses states about $900,000 a year for performing surveillance inspection work.

Import Activities

Egg products may be imported only from countries with an egg products inspection system meeting the standards of the U.S. system. As of September 1989, only Canada and The Netherlands met this requirement. During fiscal year 1989, about 3 million pounds of egg products in 104 shipments imported from these 2 countries went to 25 different U.S. locations. AMS monitors the incoming products and routinely tests the products for salmonella and various environmental contaminants. AMS took about 210 samples for testing purposes from the 104 shipments imported in fiscal year 1989.

All shell eggs imported during fiscal year 1989 were specifically for use in producing egg products. As a result, they were processed under continual AMS inspection. During this time, about 659,500 30-dozen cases of

shell eggs entered the United States from Finland, East Germany, West Germany, Israel, The Netherlands, and Sweden. The eggs were processed at 5 egg-processing plants under the supervision of 11 AMS egg products inspectors. Additionally, about 21,300 30-dozen cases of hatching eggs were imported from Canada, England, Ireland, and The Netherlands.

Export Activities

Shell eggs and egg products may be exported without special USDA certification, provided that none is required by the destination country. However, when a country requires special certification, AMS personnel determine compliance and certify, under authority of the Agricultural Marketing Act, that the country's specifications are met before the eggs or egg products are shipped.

In fiscal year 1989, AMS certified about 567,000 30-dozen cases of shell eggs as meeting the requirements of Hong Kong, Mexico, Taiwan, and the United Arab Emirates. The eggs were supplied by 44 shell egg plants, each staffed by 1 or more USDA graders.

In the same year, egg products shipped to only one country—West Germany—required special inspection. AMS certified about 112,000 pounds of egg products as meeting West Germany's import requirements. One egg-processing plant, under continual USDA inspection, produced all of the products.

Inspection Data

Table 4.1 contains AMS shell egg and egg products inspection data for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990. AMS estimated that the wholesale value of the products handled under this program amounted to $3.5 billion for fiscal year 1988 and $4.2 billion for fiscal year 1989.

Table 4.1: AMS Shell Egg and Egg Products Inspection Data, Fiscal Years 1988-90

	Fiscal year		
Activity	**1988**	**1989**	**1990 (est.)**
Egg products inspected (billions of pounds)	1.7	1.6	1.6
Egg product plants	86	83	86
Egg-handler surveillance visits	9,723	8,769	8,200
Laboratory samples analyzed			
Food chemistry and microbiology	46,481	40,969	42,000
Chemical residues	384	517	500

Source: AMS

Compliance and Enforcement Activities

AMS closed about 305 cases involving health, safety, and quality issues relating to shell eggs and egg products during fiscal years 1988 and 1989. In fiscal year 1988, 131 cases involved health and safety, and 11 cases involved quality. In fiscal year 1989, AMS estimated that it closed 147 health and safety cases and 16 quality cases. Table 4.2 shows the resolution of the closed cases by type of penalty.

Table 4.2: Compliance and Enforcement Cases Closed by AMS During Fiscal Years 1988-89

Penalty	Cases closed
Letter of information	197
Letter of warning	86
Closed without penalty	21
Criminal prosecution	1
Total	**305**

Source: AMS

Commodity Standardization Program

The Commodity Standardization Program aids in the marketing of agricultural commodities by providing (1) a common language of trade to ensure uniformity in grading and certifying commodities and (2) a means of measuring value to establish prices. Four AMS commodity divisions—Dairy, Fruit and Vegetable, Livestock and Seed, and Poultry—carry out standardization activities relating to food products.

USDA standards are the uniform measures of the quality and condition of agricultural commodities. Commonly recognized standards include USDA Grade AA for butter, USDA Grade Choice for beef, and USDA Grade U.S. No. 1 for many fruits and vegetables. Uniform standards provide identification, measurement, and control of quality characteristics important to the marketing function.

AMS works with industry, trade associations, academia, consumer groups, and state departments of agriculture to develop or modify grading standards. Three basic principles govern standards' development: (1) there must be a need, (2) there must be industry interest and support because the use of USDA standards in grading is largely voluntary, and (3) they must be practical to use.

Under the Dairy Standards Program, standards are established for butter, cheese, dry milk, and related products. AMS has also promulgated General Specifications for Dairy Plants Approved for USDA Inspection and Grading Services, which establishes the requirements for USDA-

approved dairy plants. These requirements include criteria concerning facilities, raw materials, equipment, and operating methods. As of May 1, 1990, 67 international and U.S. standards were in effect, covering 12 dairy products.

AMS has developed for state use "Recommended Requirements for Milk for Manufacturing Purposes and Its Production and Processing." These recommended requirements are intended to promote, through state adoption and enforcement, uniformity in state dairy laws and regulations, as well as national uniformity in the sanitary manner in which milk for manufacturing purposes is produced and processed. Grade A milk, which is used mainly for drinking purposes, is under FDA purview.

AMS has no legal responsibility for enforcing these recommended requirements in a state. Each state is responsible for enforcement after it has adopted the requirements. However, under the Agricultural Marketing Act of 1946, AMS assists the states in an advisory and interpretive capacity. In addition, AMS reviews the progress made toward adopting these recommended requirements. Manufacturing-grade milk is produced in 29 states. Each year, AMS Dairy Division representatives visit about 10 states to evaluate a random sampling of the states' manufacturing-grade milk producers.

Under the Fruit and Vegetable Standards Program, standards are established for fresh and processed fruits, vegetables, and specialty crops, including nuts. The standards usually define such factors as color, shape, size, maturity, and the number and degree of defects. Flavor and texture are also rated for some products, especially those that are processed. As of September 30, 1989, 157 U.S. grade standards covering 85 fresh fruit and vegetable commodities and related foods were in effect. Also on that date, 157 U.S. grade standards covered 74 processed fruit, vegetable, and related products.

The Livestock and Meat Standardization Program's primary purpose is to provide meat graders and market reporters with the standards and specifications to be used in the grading, certification, and market reporting of livestock (e.g., cattle, sheep, and swine) and meat; and to ensure their effectiveness in providing a nationally understood language of commerce. During fiscal year 1989, 30 international and U.S. grade standards covered 6 livestock commodities.

Under the Poultry Standards Program, grade standards are developed and revised for poultry, poultry products, shell eggs, and rabbits. Commodity purchase and federal specifications are also developed. During fiscal year 1989, 10 U.S. grade standards were in effect, covering 4 commodities.

Commodity Inspection and Grading Program

The Commodity Inspection and Grading Program is intended to facilitate the interstate and foreign commerce of agricultural products. This is accomplished by inspecting, identifying, and certifying the quality of these products in accordance with official standards. Grades serve as the basis for prices and reflect the product's value to the farmer and the buyer. Each of AMS' four food commodity divisions carries out commodity inspection and grading activities.

Inspection and grading services are generally voluntary, rather than mandatory or regulatory, and recipients pay for the requested service. AMS inspection and grading activities are carried out by (1) inspectors, graders, and classers assigned to regional offices, field offices, and laboratories, which are geographically located according to the industry being served, or (2) licensed state/commonwealth employees under agreements with those governments.

Dairy Inspection and Grading

AMS carries out dairy inspection and grading activities through three programs—plant surveys, inspection and grading, and resident grading and quality control—which are directed at evaluating the wholesome production, quality, manufacture, and distribution of dairy products. About 700 establishments are eligible for dairy inspection and grading services.

Each plant survey is made by a dairy inspector, who makes detailed checks on more than 100 items. A plant survey informs the plant manager about the factors affecting the quality and wholesomeness of the finished product—quality of raw material, sanitation, condition of plant and equipment, and processing procedures. Associated with the plant surveys is the equipment review process, which evaluates the sanitary design of processing equipment prior to its installation in the processing facility.

Grading encourages manufacturers to produce uniformly high-quality, stable products that will bring top prices. The manufacturer, in turn, encourages the producer to produce top-quality milk and cream.

Resident grading and quality control service, available to approved plants, is a combination of the plant survey, inspection and grading, and laboratory programs. An inspector stationed at the plant on a full-time basis performs quality checks on plant and equipment sanitation and grades and certifies the finished product.

Inspection and grading data. Table 4.3 shows dairy inspection and grading program data for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990. AMS' Dairy Division does not maintain records of the dollar value of the dairy products produced by the inspected establishments.

Table 4.3: AMS Dairy Inspection and Grading Data, Fiscal Years 1988-90

	Fiscal year		
	1988	1989	1990 (est.)
Dairy products (millions of pounds)	3,026	1,917	1,905
Number of plant inspections	1,987	1,800	1,750

Source: AMS

Export and import activities. AMS inspection services are available to establishments that export dairy products. AMS does not maintain records of the number of requests, locations, or samples destined for export. AMS has no involvement with dairy product imports, which are under FDA jurisdiction.

Fruit and Vegetable Inspection and Grading

For fresh products, AMS offers commercial shippers shipping point inspection for quality and condition of fresh fruits, vegetables, nuts, and other miscellaneous products. This inspection establishes the commodities' quality at the time of shipment for sales purposes or verifies compliance with contract terms.

Receivers in terminal markets can have AMS inspect shipments for both quality and condition or for condition only. Many receivers use this inspection to determine whether or not an arriving shipment meets contract terms, to help them decide the best use for a particular shipment, or to aid them in selling their produce.

For processed products, AMS performs inspection and/or grading services on either an in-plant or lot inspection basis, depending on the applicant's wishes and the special requirements of the particular contract or program. In-plant inspection is done during the manufacturing process and involves observing the condition and acceptability of raw material, monitoring plant sanitation, performing on-line checks of the

product at various stages of processing, and final grading of the finished product. Lot inspection involves drawing samples from specifically identified lots and determining the grade of the lots on the basis of examination and testing of the samples.

For both in-plant and lot inspection, microscopic and other special tests and analyses are often required before AMS certifies the product's quality and condition.

Fruit and vegetable establishments are not subject to mandatory inspection, although a firm may contract for continuous in-plant AMS inspection if it wishes to do so. Most fruit and vegetable quality inspections are done on a voluntary basis wherever the product is located. The inspection location is specified by the party requesting the service; for fresh products, it can be the shipper's loading dock, receiver's store, port facility, etc. Generally, fresh inspections occur in the vicinity of 1 of the approximately 130 federal-state shipping point inspection offices, 32 federal receiving markets, or the 100 federal-state collaborator receiving markets.

Processed fruit and vegetable inspections may be done at the processing plant, or samples may be taken to an inspection office for analysis. For processed products, AMS has 21 area field offices and 16 suboffices and inspection points. During fiscal year 1989, AMS had inspection contracts with 323 processors and 3,346 active accounts for processed inspections.

Relationship to state inspection programs. For fresh products, AMS has cooperative agreements in all 50 states and Puerto Rico. Under these agreements, AMS supervises and trains state inspectors in methods of interpreting and applying U.S. grades, performing inspections, and preparing official U.S. certificates. AMS licenses those employees it considers qualified to serve as inspectors. The total number of state employees licensed on an annual basis is in excess of 5,500, representing about 2,500 staff years. AMS may also appoint licensed state inspectors to serve as collaborators so that they may inspect products that originate in states other than the one where the inspection is conducted. AMS has appointed about 350 such employees as collaborators.

For processed products, federal employees perform the bulk of inspection activities. However, AMS has formal agreements with the Hawaii and Virginia state inspection programs and Puerto Rico. Under these

agreements, AMS provides federal supervision of state employees and is reimbursed for supervisory expenses by the states or Puerto Rico.

Import activities. Section 8e of the Agricultural Marketing Agreement Act requires that certain imported fruits and vegetables meet the same quality requirements as domestic products during the effective periods of domestic marketing order regulations. These commodities, which are to be inspected for quality before clearing customs, are avocados, dates (other than for processing), filberts, grapefruit, table grapes, limes, olives (other than Spanish-style olives), onions, oranges, Irish potatoes, prunes, raisins, tomatoes, and walnuts. As of October 1990, legislation to add apples, kiwifruit, plums, nectarines, papayas, and pistachios was pending.

The importer is responsible for contacting AMS to request inspection of these imported products. The United States Customs Service is required to hold the products until AMS certifies that they meet section 8e import requirements.

Whether mandatory under section 8e or voluntary upon request, AMS inspections may occur at any port of entry. For fresh fruits and vegetables, the greatest volumes of imports are inspected at six locations—Los Angeles and Otay Mesa, California; Nogales, Arizona; Reynosa and McAllen, Texas; and Philadelphia, Pennsylvania. Data on the number of import inspectors and amount of imported products inspected are not available because inspectors are not assigned specifically to imports and only aggregate figures of imported and domestic products are maintained.

Agriculture Canada (USDA's counterpart in Canada) is an authorized inspection agent for certifying onions, potatoes, and tomatoes destined for import into the United States. Therefore, AMS does not usually inspect these commodities for compliance with section 8e requirements. However, under the Food Security Act of 1985 (P.L. 99-198), U.S. federal-state inspectors conduct spot-check inspections of imported Canadian potatoes at border points in Maine on a restricted basis. In the 1988-89 season, 414 inspections were made for section 8e requirements and labeling requirements under the Perishable Agricultural Commodities Act.

Export activities. AMS certifies, under the Export Apple and Pear Act and the Export Grape and Plum Act, that exported apples, grapes, and pears meet certain minimum quality standards. (Plums are not currently

regulated.) In addition, AMS and designated state inspectors are authorized by Agriculture Canada to certify the quality of 27 fresh fruit and vegetable commodities which are required to meet minimum quality requirements before being allowed into Canada. AMS does not maintain data on inspection of export shipments or the number of inspectors involved in certifying the quality of fruit and vegetable exports.

Inspection and grading data. Table 4.4 shows fruit and vegetable inspection and grading data for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990. AMS' Fruit and Vegetable Division does not have an official estimate of the value of the fruits and vegetables inspected and graded.

Table 4.4: AMS Fruit and Vegetable Inspection and Grading Data, Fiscal Years 1988-90

Activity	Fiscal year 1988	1989	1990 (est.)
Inspection grading			
Fresh fruits and vegetables (billions of pounds)	74.6	74.7	75.0
Processed fruits and vegetables (billions of pounds)	8.7	8.7	8.8
Laboratory analyses of processed products (thousands)	173	210	195

Source: AMS

Meat Grading and Certification

For meat, AMS provides quality- and yield-grading services and certification services. Quality grades, such as USDA Prime and USDA Choice, identify the palatability (tenderness, juiciness, and flavor) of meat. Yield grading indicates the amount of usable meat a carcass will yield after the waste fat and bone have been trimmed off.

The meat certification service provides large-volume purchasers with consistent and uniform meat and meat products, regardless of the meat supplier. Products, such as ground beef, steaks, roasts, frankfurters, and other meat items are examined by meat graders to ensure that the products conform to the purchasers' contract requirements.

AMS may perform voluntary grading and certification services in any of the approximately 6,700 establishments operating under Food Safety and Inspection Service regulations. The frequency of services for the establishments that receive voluntary grading and certification services from AMS ranges from daily to very infrequently.

Relationship to state grading and certification programs. AMS has cooperative agreements with 11 states regarding voluntary meat grading and certification services. For two states (Hawaii and Virginia) the agreements provide for the states to use federal meat graders to perform the requested services. For nine states (Georgia, Indiana, Louisiana, Maine, Montana, New York, North Carolina, Utah, and Vermont), state employees trained and supervised by AMS perform the requested services.

Import and export activities. For meat and meat products, imports and exports are regulated by FSIS, pursuant to the Federal Meat Inspection Act.

Grading and certification data. Table 4.5 shows meat grading and certification data for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990. AMS estimated that the value of meat products handled in fiscal year 1988 amounted to $37 billion.

Table 4.5: AMS Meat Grading and Certification Data, Fiscal Years 1988-90

	Fiscal year		
Activity/commodity	**1988**	**1989**	**1990 (est.)**
Graded (millions of pounds)			
Beef	12,478	14,294	14,671
Lamb	283	289	290
Veal and calf	39	39	39
Total	**12,800**	**14,622**	**15,000**
Certified (millions of pounds)			
Meat and meat products	700	759	809

Source: AMS

Poultry Grading

AMS' principal poultry-grading activities are

- grading, identification, and certification of poultry, poultry products, shell eggs, and domestic rabbits as to class, quality, quantity, and condition;
- acceptance services;
- approval of shell egg-grading facilities; and
- approval of shell egg and poultry labels bearing the USDA grade mark.

Grading services are voluntary, and plants are subject to program requirements only if services are requested. About 190 poultry plants and 180 shell egg plants receive grading services on a full-time basis.

About 30 poultry plants and 25 shell egg plants receive grading services on a part-time basis. An undetermined number of firms request and receive lot-grading services.

AMS has cooperative agreements on poultry grading with all 50 states, Puerto Rico, and the Virgin Islands.

Export activities. AMS export activities concerning shell eggs, egg products, and poultry vary widely from year to year, depending on such factors as foreign country needs, domestic and foreign market conditions, and incentive programs, such as the Export Enhancement Program.

For foreign countries requiring special certification of shell eggs and poultry, Poultry Division grading personnel determine compliance and certify that the countries' specifications are met before the products are shipped.

In fiscal year 1988, 151,000 metric tons of whole chickens and leg quarters were certified for shipment to various foreign countries under USDA's Export Enhancement Program. In fiscal year 1989, 1,800 metric tons of product were certified by AMS for shipment to foreign countries under this program.

Grading data. Table 4.6 shows poultry-grading data for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990. AMS estimated that the wholesale value of the products handled in fiscal years 1988 and 1989 amounted to $11.2 billion and $12.8 billion, respectively.

Table 4.6: AMS Poultry-Grading Data, Fiscal Years 1988-90

	Fiscal year		
Activity	**1988**	**1989**	**1990 (est.)**
Poultry products and rabbits graded (millions of pounds)[a]	14,715	14,401	15,400
Shell eggs graded (millions of dozens)	1,689	1,557	1,518

[a]Rabbits graded amounted to less than 1.5 million pounds per year.

Source: AMS

Compliance and Enforcement Activities

Because AMS' Commodity Inspection and Grading Program services are generally voluntary in nature, compliance and enforcement become issues only when a service recipient tries to gain an unfair advantage through misuse of an AMS service. This could include such things as alteration of an official grading certificate, misrepresentation of product quality, or economic adulteration. In the last 3 fiscal years (1987-89),

AMS took a total of 80 enforcement actions with dispositions ranging from letters of warning to fines and imprisonment.

Laboratory Testing Program

Through its Laboratory Testing Program, AMS' Commodities Scientific Support Division conducts a wide range of laboratory tests on agricultural commodities to aid the commodity divisions in their inspection and grading activities. It also ensures that commercial and private laboratories used by AMS are performing tests in a consistent, uniform, and accurate manner; and it develops and tests new and improved laboratory methodologies and coordinates a laboratory safety program.

The Laboratory Testing Program has 2 multidisciplinary laboratories, 1 citrus-testing laboratory, and 10 aflatoxin laboratories. The laboratories analyze a variety of commodities, including raw meat and poultry, frozen and dried egg products, orange juice concentrate, peanut products, dairy products, fruits and vegetables, and prepackaged military meals, for compliance with federal and state specifications. Tests are done to detect natural constituents and microbiological, chemical, environmental, and pharmaceutical contaminants, as well as to determine quality and product acceptance. Quality assurance and reliability of results are maintained through on-going monitoring of AMS laboratories and private and commercial laboratories used by AMS.

Governmentwide Food Quality Assurance Program

The Governmentwide Food Quality Assurance Program is intended to develop, coordinate, and approve food product descriptions; establish uniform quality assurance policies and procedures for food procured by federal agencies; and ensure that the federal government buys its food as efficiently and economically as possible. Under this program, AMS program specialists

- establish and maintain quality assurance and specification policies and procedures for food procured by the federal government;
- establish and maintain an interagency program for coordination of specifications between users, regulatory agencies, inspection and acceptance agencies, and industry;
- ensure compliance with laws and regulations in the development of food specifications;
- review and approve all food specifications developed by USDA and other federal agencies; and
- maintain an inventory of food purchase specification documents used by federal agencies.

The program has approved federal governmentwide specifications for such products as frozen ground beef products, ready-to-cook chilled and frozen chicken, and dehydrated white potatoes. A single document is now used by all federal agencies to procure these products. Since fiscal year 1981, 125 Commercial Item Descriptions for food products have been developed and approved.

Inspection/Grading Workload Data, Fiscal Years 1980, 1985, and 1989

Table 4.7 shows selected AMS inspection and grading workload data for fiscal years 1980, 1985, and 1989 to illustrate the changes in workload during the 1980s.

Table 4.7: Selected AMS Inspection/ Grading Workload Data, Fiscal Years 1980, 1985, and 1989

	Fiscal year		
Product inspected/graded	**1980**	**1985**	**1989**
Egg products (billions of pounds)	1.1	1.3	1.6
Shell eggs (billions of dozens)	2.1	1.8	1.6
Dairy products (billions of pounds)	3.4	4.4	1.9
Fresh fruits and vegetables (billions of pounds)	72.9	71.6	74.6
Meat products (billions of pounds)	12.3	13.1	14.6
Poultry products and rabbits (billions of pounds)	12.1	12.7	14.4

Source: AMS

Funding Levels

AMS' food safety and quality activities are funded through a combination of appropriated funds and user fees. Federal appropriations fund the Governmentwide Food Quality Assurance Program, standardization activities, and the mandatory provisions of the Egg Products Inspection Act. User fees fund AMS' voluntary commodity inspection and grading activities.

Table 4.8 shows AMS' actual obligations for its food safety and quality activities for fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990.

Table 4.8: AMS Obligations for Food Safety and Quality Activities, Fiscal Years 1988-90

Dollars in thousands

	Obligations		
Program	**1988**	**1989**	**1990 (est.)**
Shell Egg Surveillance and Egg Products Inspection	$9,711	$9,918	$10,239
Standardization	2,330	2,270	2,461
Commodity Inspection and Grading	81,700	81,815	82,272
Laboratory Testing[a]	—	2,178	3,639
Governmentwide Food Quality Assurance	772	777	777
Total	**$94,513**	**$96,958**	**$99,388**

[a]In fiscal year 1988 and part of 1989, Laboratory Testing Program obligations were charged to the other AMS food safety and quality programs.

Source: AMS

Staffing Levels

AMS, headquartered in Washington, D.C., had about 310 year-round and seasonal field offices during fiscal year 1989. As of September 30, 1989, AMS had 3,470 full-time employees and 1,357 other employees, of which 2,825 of the former and 1,334 of the latter were assigned to field office locations.

AMS has a permanent, full-time staff of about 2,400 working on food safety and quality activities. In addition, AMS employs hundreds of seasonal or intermittent workers and obtains the services of thousands of others through cooperative agreements, mostly with state departments of agriculture.

Table 4.9 shows the actual staff years AMS expended on food safety and quality activities during fiscal years 1988 and 1989 and the estimated amounts for fiscal year 1990.

Table 4.9: AMS Staff Years for Food Safety and Quality Activities, Fiscal Years 1988-90

Program	Fiscal year 1988	1989	1990 (est.)
Shell Egg Surveillance and Egg Products Inspection			
Federal	203	201	199
State	47	45	44
Standardization	41	39	42
Commodity Inspection and Grading			
Federal	2,090	2,070	2,005
State	313	324	322
Laboratory Testing[a]	•	50	81
Governmentwide Food Quality Assurance	12	12	12
Total	**2,706**	**2,741**	**2,705**

[a]In fiscal year 1988 and part of 1989, Laboratory Testing Program staffing was included in the other AMS food safety and quality programs

Source: AMS

Coordination With Other Federal Agencies

AMS coordinates with five USDA agencies and nine other federal agencies to avoid duplication of effort, conflicting actions, or overlapping jurisdiction in carrying out its food safety and quality activities.

Within USDA, AMS coordinates with the Agricultural Research Service, Animal and Plant Health Inspection Service, Cooperative State Research Service (CSRS), Federal Grain Inspection Service, and the Food Safety and Inspection Service.

In the Governmentwide Food Quality Assurance Program, AMS coordinates with the Bureau of Prisons, the Department of Defense, the Department of Veterans Affairs, the Indian Health Service, and the National Institutes of Health.

The remainder of this section discusses AMS coordination with other federal agencies for fruit and vegetable products; poultry, shell eggs, and egg products; dairy products; meat products; and the salmonella interagency task force.

Fruit and Vegetable Products

AMS coordinates its quality inspection activities for imported fresh and processed fruits, vegetables, and related products with the United States Customs Service and FDA and its inspections of processed foods with FDA, the Department of Defense, the National Marine Fisheries Service, and

FGIS. AMS is also party to the memorandum of understanding with FSIS, FDA, and EPA on regulatory activities concerning residues of drugs, pesticides, and environmental contaminants in foods. (See part 1.)

Poultry, Shell Eggs, and Egg Products

USDA has exclusive jurisdiction for inspecting egg products in official egg products plants operating under mandatory egg products inspection. However, a limited number of egg products plants also process foods that are regulated by the requirements of the Federal Food, Drug, and Cosmetic Act; Federal Meat Inspection Act; or Poultry Products Inspection Act (PPIA). Accordingly, these plants' operations are subject to inspection by FDA and FSIS, as well as AMS.

Shell egg-packing plants are subject to inspection by AMS and FDA. Under the Shell Egg Surveillance Program, USDA inspects shell egg-packing plants at least four times each calendar year to determine compliance with Egg Products Inspection Act requirements. These plants are also regulated by FFDCA provisions and, therefore, are subject to FDA inspection. In plants where AMS voluntary poultry-grading services are provided, PPIA regulations for poultry plants apply.

Dairy Products

AMS, FDA, and state agencies make similar inspections of dairy plants. USDA inspections concentrate on issues such as sanitation; facilities; and product safety, stability, and quality, which are important factors in a product-grading system. FDA and state inspections focus mainly on checking and enforcing minimum standards of operation regarding product safety, sanitation, facilities, licensing, and weight control.

Under a memorandum of understanding with FDA, AMS has carried out a salmonella surveillance program at dry milk product plants for over 25 years. (See part 1.) The program involves quarterly testing of product and environmental samples, together with a detailed system of follow-up in the event of positive results. AMS keeps FDA informed about the overall testing program and about testing in progress at plants that are experiencing salmonella control problems. The incidence of positive results in routine testing is less than one-fourth of 1 percent.

Meat Products

AMS provides voluntary meat quality services (grading) to the livestock and meat industry. These services are generally rendered at meat-packing plants. Within these same plants, FSIS provides mandatory regulation of the meat industry. AMS has developed a close relationship with

FSIS to accomplish the missions of both programs. One example is an interagency memorandum of understanding that authorizes AMS personnel to retain products, in the absence of an FSIS inspector, that may be in violation of meat inspection regulations.

Similarly, FSIS has legislative responsibility to control the labeling of meat products, including grade labeling. FSIS assists in maintaining the integrity of the AMS meat quality grades by approving only labels that honestly represent the product's grade.

Salmonella Interagency Task Force

AMS served as the coordinator of a USDA/FDA interagency task force established to reduce the possibility of outbreaks of salmonella enteritidis in humans and domestic poultry flocks. USDA agencies cooperating with AMS include APHIS, ARS, CSRS, and FSIS.

Task force efforts have resulted in a comprehensive plan, which includes a voluntary flock-testing program, a public awareness campaign, and cooperative research efforts.

In February 1990, USDA implemented a mandatory flock-testing program conducted by APHIS. As a result, APHIS now serves as the USDA coordinator of the USDA/FDA interagency task force.

Critical Food Safety and Quality Issues Facing AMS During the 1990s

According to AMS, some of the most critical food safety and quality issues it may be involved in during the 1990s include

- microbiological contamination,
- residue contamination,
- biotechnology,
- voluntary pesticide residue testing,
- mandatory quality inspection for imported fruits and vegetables,
- international harmonization of food regulations,
- nutritional content of food, and
- other issues (e.g., growth-promoting hormones in food animals and food irradiation).

Microbiological Contamination

Although chemicals and food safety have been in the spotlight recently, AMS believes that microbiological contamination contributes to more significant health problems. Although great progress has been made in

identifying and preventing some foodborne diseases, outbreaks of microbial origin continue to persist or are on the rise. Also, previously unrecognized pathogenic microorganisms are being acknowledged, and new techniques in food processing and preservation portend new types of safety and wholesomeness issues.

USDA, in conjunction with FDA and outside experts, has established a National Advisory Committee on the Evaluation of Microbial Criteria for Food. The Committee is tasked to recommend microbiological standards applicable to foods under each federal agency's jurisdiction. The standards will be used in the agencies' regulatory processes or quality assessments. Also, the Committee will address the use of a Hazard Analysis and Critical Control Point system for specific commodities. The system consists of identifying, assessing, monitoring, and controlling hazards associated with growing, harvesting, processing, marketing, preparing, and using a given raw material or food product.

Residue Contamination

AMS said that chemical contamination also is high on its agenda for the future. Its strategy for residue control is to help industry prevent the incidence of residues and to use more rapid tests to detect residues when they are present. AMS believes that prevention is the most efficient and cost effective course of action. It also believes that a need exists for a centralized pesticide residue information data base that can be used to communicate objective, comprehensive information on those residues to the public.

Biotechnology

AMS stated that the potential impact of biotechnologies on agricultural productivity and product quality is entering a revolutionary period. Key advances are being made in the areas of (1) genetically engineered pharmaceuticals designed to promote animal growth, cause selective partitioning of nutrients, and improve animal product quality; (2) vaccines against animal diseases; (3) mass production (in vitro) of identical embryos by using transgenic material to enhance animal product quality, quantity, or production efficiency; (4) genetically engineered crops that fix their own nitrogen; and (5) the development of biological pesticides for or actually part of plants. AMS believes that these innovations will enable the agricultural community to achieve greater or safer production, better utilize products, and address worldwide food inadequacy problems.

Voluntary Pesticide Residue Testing

According to AMS, the U.S. produce industry is debating whether fresh fruits and vegetables should be tested for pesticide residues on a voluntary basis. Some parties fear that such a practice would be used as a marketing tool, implying that untested produce is unsafe. There also is concern that some third-party testing companies do not offer their services to all interested customers in a geographic area.

Mandatory Quality Inspection for Imported Fruits and Vegetables

Legislation has been proposed to expand the list of commodities under Section 8e of the Agricultural Marketing Agreement Act, whose imports must meet minimum quality standards during the effective period of domestic marketing orders. AMS believes that the trend toward mandatory quality inspections for imports may expand in the future.

International Agreement

AMS said that many efforts are ongoing involving international agreement—technically called harmonization—of technical regulations relating to food, such as those addressing pesticides residues, phytosanitary requirements, packaging, and labeling. Other organizations involved with efforts to harmonize technical requirements for food include the Codex Alimentarius Commission, the Organization for Economic Cooperation and Development, and the Economic Commission for Europe.

Nutritional Content of Food

With the growing emphasis on health and nutrition, demand is increasing for improved nutritional labeling and reducing the amounts of sodium, fat, and cholesterol in food. In addition, food companies are continuing to use health messages in advertising and on labels.

Other Issues

Examples of other food safety and quality issues that AMS is or could become involved in include the use of growth-promoting hormones in food animals, mandatory fish inspection, groundwater contamination, pesticides under special review by EPA, microwave cooking, fat substitutes, food irradiation, aflatoxin and other molds, rapid-testing methodology and approvals, foodborne microorganisms and their toxins, detection and quantification of foodborne viruses, mycotoxin contamination of food commodities, and veterinary drug residues in egg products.

Federal Grain Inspection Service Activities Relating to Safety and Quality of Grain, Rice, and Related Commodities

USDA's Federal Grain Inspection Service's primary mission is to facilitate the marketing of grain, oilseeds, pulses (e.g., peas), rice, and related commodities by, among other things, (1) establishing descriptive standards and terms, (2) accurately and consistently certifying quality, and (3) providing for uniform official inspection and weighing.

FGIS' food safety and quality activities include (1) helping ensure food safety by inspecting corn, sorghum, and rice for aflatoxin; (2) developing and disseminating information about chemical residues in grain which is used by other agencies to establish permissible levels of pesticides in grain at the marketplace; and (3) helping ensure food quality by inspecting the quality of domestic and exported grain.

Major Legislation

FGIS is responsible for administering the U.S. Grain Standards Act (USGSA), as amended (7 U.S.C. 71 et seq.), and providing inspection and weighing services for rice and grain-related products under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.).

To help advance the orderly and efficient marketing and effective distribution of grain and related products to domestic and foreign buyers, FGIS develops and enforces standards that measure and describe the commodities' physical and biological properties and promotes their use as a language of commerce. The standards provide buyers and sellers, who may never see each other, an understanding and assurance of what is being traded. FGIS is responsible for ensuring that these standards are applied fairly and accurately and thereby promotes and protects such commerce. Under USGSA, FGIS has established standards for 11 grains—barley, corn, flaxseed, mixed grain, oats, rye, sorghum, soybeans, sunflower seed, triticale, and wheat.

USGSA

- requires a national inspection and weighing system for grain;
- requires that, with few exceptions, export grain be inspected and weighed;
- provides for inspection and weighing services for domestic grain on request;
- prohibits deceptive practices and criminal acts with respect to the inspection and weighing of grain; and
- provides penalties for violations.

USGSA was amended in 1981 to require FGIS to collect user fees from official agencies (states and private agencies which perform inspection and weighing services) to fund the costs associated with supervising the federal grain inspection and weighing activities of official agencies.

The Agricultural Marketing Act of 1946 requires FGIS to provide, on request and for a fee, official inspection and weighing services for domestic and export shipments of rice and grain-related products. The commodities covered by the act include dry beans, dry peas, hops, lentils, processed grain products, pulses, rice, and related commodities.

Organizational Units and Responsibilities

During fiscal year 1989, FGIS carried out its inspection and weighing services through headquarters staffs in Kansas City, Missouri, and Washington, D.C., and a field staff comprising 27 field offices, 2 federal-state offices, and 8 suboffices.

FGIS also used 20 states and 57 private agencies designated to provide official services at interior points. Of these, eight states are also delegated to perform official inspection and weighing services at export points.

The FGIS organizational units involved directly with food safety and quality activities are the (1) Quality Assurance and Research Division, (2) Field Management Division, (3) International Monitoring Staff, and (4) Compliance Division. Their responsibilities are discussed below.

Quality Assurance and Research Division

The Quality Assurance and Research Division is responsible for

- developing new objective tests and methods for determining grain quality,
- providing reference standards for FGIS methods and developing new reference standards as required,
- developing criteria and recommending specifications for electronic instrumentation to improve the reliability of grain inspection,
- developing and maintaining an agencywide quality control program covering all aspects of grading and inspection,
- developing and carrying out an equipment approval program,
- developing and maintaining an agencywide quality assurance sample program,
- maintaining uniform application of standards for grains and commodities,

- rendering final decisions on inspection appeals, and
- conducting technical training for field personnel.

According to FGIS, the Division will play a major role during the next 5 years in moving FGIS toward more objective testing to replace subjective tests for grain quality. To help ensure such a move, the Division will continue to improve the monitoring of existing test methods, update reference methods as scientific procedures change, develop specifications for electronic instrumentation, initiate and carry out an instrument-type evaluation and approval program, and implement a quality control program covering all aspects of grain grading and equipment check testing. Further, major emphasis will be placed on technical training of field personnel.

Field Management Division

The Field Management Division is responsible for

- directing the operations of FGIS field offices;
- developing inspection and weighing policies and procedures;
- establishing the U.S. standards for grain, pulses, rice, and other commodities;
- overseeing delegated and designated agencies; and
- monitoring the quality of grain as it moves through the market.

FGIS said that, during the next 5 years, the Division must concentrate on advancing new testing and automated data processing technology into the daily operations of the national inspection service.

International Monitoring Staff

The International Monitoring Staff administers the monitoring program for U.S. grain shipments exported to foreign nations to evaluate whether the quality and weight of grain received by foreign importers is comparable (within expected variation) to the quality and weight certified upon official inspection in the United States. In doing so, it investigates foreign complaints on grain quality, meets with foreign purchasers of U.S. grain to gather information about the quality of U.S. grain they import, conducts educational briefings for importers, and coordinates FGIS activities involving foreign travel. One overall objective is to continually enhance the credibility and image of FGIS in the international grain marketplace.

Compliance Division

The Compliance Division is responsible for ensuring that USGSA; applicable provisions of the Agricultural Marketing Act of 1946; and regulations, procedures, and policies issued under the acts are implemented accurately and uniformly. Its responsibilities include

- conducting operational reviews and program evaluations,
- conducting investigations of alleged program violations,
- implementing enforcement actions, and
- administering other related regulatory programs.

Program Activities

FGIS' food safety and quality activities are conducted through its national grain inspection and weighing system. These activities are discussed below under the following captions: inspection services, inspection and weighing activities, export activities, foreign grain complaints, and relationship to state inspection programs.

Inspection Services

Official inspection is defined as the determination and certification by official personnel of (1) the kind, class, quality, or condition of grain under standards provided for in USGSA; (2) the condition of vessels and other carriers or receptacles for the transportation of grain insofar as it may affect the quality of such grain; or (3) other facts relating to grain under other criteria approved by the FGIS Administrator.

FGIS offers three types of official grain inspection services, which differ only in the way grain is sampled. Each type is identified by a certificate of a specific color. Official Sample-Lot Inspection is the only one in which official personnel licensed or employed by FGIS, using approved equipment, obtain representative samples. The results, issued on a white certificate, represent the entire lot inspected. This service is required for export inspection and is available for domestic inspection. Under Warehouse Sample Lot Inspection, FGIS licenses grain elevator employees to sample grain with approved equipment. The results, issued on a yellow certificate, represent the entire lot inspected. For Submitted-Sample Inspection, the applicant obtains and submits the sample. The official personnel inspect the sample and issue a pink certificate. The results issued represent only the sample submitted. All officially inspected samples are analyzed by trained official inspectors who are licensed or employed by FGIS.

Other services available on request include (1) determinations of protein in wheat, oil in sunflower seeds, protein and oil in soybeans, ethylene

dibromide residues in grains and processed commodities, and aflatoxin in corn; (2) stowage exams (made within 24 hours before loading) to ensure that carriers are clean, dry, and fit for loading; and (3) equipment testing to ensure accurate inspection results.

Inspection and Weighing Activities

Under USGSA, exported grain, with few exceptions, must be officially weighed. A similar requirement exists for inspection except for grain which is not sold or described by grade. Grain exporters that export less than 15,000 metric tons annually are exempt from the act's mandatory official inspection and weighing requirements, as is grain exported by rail or truck to Canada or Mexico.

Mandatory services. During fiscal year 1989, FGIS provided mandatory official inspection and weighing services, on a fee basis, at 61 export grain elevators by about 550 FGIS employees. Also, 8 delegated states with about 2,085 employees provided official services at an additional 27 export grain elevators under direct FGIS oversight.

Permissive services. Official inspection and weighing of U.S. grain destined for domestic consumption, with few exceptions, are performed on request and require payment of a fee by the applicant for the services. In fiscal year 1989, domestic inspection and weighing services were provided by 77 designated state and private agencies. These agencies employed about 4,210 personnel who were licensed by FGIS to provide such services in accordance with FGIS regulations and instructions.

Inspection and standardization activities under the Agricultural Marketing Act of 1946, which cover such commodities as flour and corn meal, pulses, and rice, are performed on request and for a fee for both domestic and export shipments either by FGIS employees or individual contractors, or through cooperative agreements with states. Services provided include grain fumigation inspections, aflatoxin testing, sampling, checkweighing, checkloading, and quality analysis for various commodities.

Establishments subject to inspection. During fiscal year 1989, FGIS inspected 319 (about 40 percent) of the approximately 740 establishments handling food products that were subject to FGIS inspection. All facilities are not regularly inspected because inspection is required only when an applicant requests FGIS services or when a contract requires the inspection.

Export Activities

During fiscal year 1989, about 630 inspectors were available for grading export grain. About 280 were FGIS grain inspectors at export field offices, and about 350 were employees of the 8 delegated states. During the year, the inspectors performed services at 103 export service points and graded 94,619 samples of exported grain.

Foreign Grain Complaints

In fiscal year 1989, FGIS received 24 quality complaints and 1 quantity (weight) complaint. The tonnage involved in the complaints represented about 0.9 percent, by weight, of the total amount of grain exported during the year. The complaints involved allegations of heat damage, infestation, and damaged kernels in wheat; broken corn and foreign materials in corn; and the presence of aflatoxin in corn.

Relationship to State Inspection Programs

In fiscal year 1989, the following eight states were delegated to provide original inspection and weighing services under USGSA at export port locations and were designated to provide official services under USGSA at interior locations: Alabama, California, Minnesota, Mississippi, South Carolina, Virginia, Washington, and Wisconsin.

In addition, 12 other states were designated to provide official services under USGSA at interior locations only.

FGIS had agreements with 19 states, Puerto Rico, and Canada. The state agreements involve inspection and sampling services performed by state personnel. The Puerto Rico agreement involves rice inspection services performed by Puerto Rico Commonwealth employees. The agreement with the Canadian Grain Commission sets forth the conditions under which FGIS official personnel will inspect U.S. grain in Canadian elevators.

Funding Levels

FGIS activities are funded by federal appropriations, user fees, and interest on user fees. User fees fund FGIS' inspection and weighing activities, while federal appropriations fund FGIS' standardization and compliance activities, international monitoring, and the FGIS Advisory Committee.

For fiscal years 1984-89, about 82 percent of FGIS' total annual expenditures were funded by user fees and about 18 percent by federal appropriations. Table 5.1 shows FGIS' appropriated and fee-supported expenditures for fiscal years 1987 through 1989.

Table 5.1: FGIS' Appropriated and Fee-Supported Expenditures, Fiscal Years 1987-89

Dollars in Millions

	Fiscal year		
Expenditures	**1987**	**1988**	**1989**
Appropriated funds	$6 7	$6 8	$7 5
Fee supported funds	29 5	31 1	34 8
Total	**$36.2**	**$37.9**	**$42.3**

Source FGIS Annual Report to Congress, 1989

Staffing Levels

Table 5.2 shows FGIS' full-time permanent and part-time employee staffing at the end of fiscal years 1987 through 1989.

Table 5.2: FGIS Full-Time Permanent and Part-Time Employee Staffing Levels at End of Fiscal Years 1987-89

	Fiscal year		
Employee type	**1987**	**1988**	**1989**
Full-time permanent	690	709	750
Part-time	161	152	110
Total	**851**	**861**	**860**

Source FGIS budget data

As of September 30, 1989, FGIS had about 84 percent of its full-time employees and 91 percent of its part-time employees assigned to field locations. The remaining full-time employees (16 percent) and part-time employees (9 percent) were at headquarters.

Table 5.3 shows FGIS full-time permanent staffing, expenditures, and inspection activities for selected fiscal years.

Table 5.3: FGIS Resources and Inspection Activities, Fiscal Years 1980, 1985, and 1989

	Fiscal year		
Description	**1980**	**1985**	**1989**
Expenditures (millions)	$56 6	$38 5	$42 3
FGIS full-time permanent staffing	1,778	730	750
Grain officially inspected (million metric tons)	278 5	269 1	297 7
Inspections, reinspections (millions)	4 6	3 0	2 8
Protein inspections (thousands)	804 3	571 3	526 6
Aflatoxin inspections (thousands)	4 3	20 3	49 2

Source FGIS

Coordination With Other Federal Agencies

During 1989, FGIS had 36 written cooperative agreements relating to food safety and quality activities. At the federal level, it had 1 agreement with a non-USDA agency—FDA—and 14 agreements with other USDA agencies.

The agreement with FDA, which also is discussed in part 1, involves FDA's and FGIS' inspection and standardization responsibilities relating to grain, rice, pulses, and food products at facilities that process, hold, and distribute such products. FGIS has no authority to seize or detain these products when it discovers anything that would endanger public health during its inspections. Under this agreement, FGIS reports to FDA any lots of these products which it considers to be actionable under the Federal Food, Drug, and Cosmetic Act. Lots are actionable if they contain animal or insect filth, toxic substances, objectionable odor, deleterious foreign matter, nonapproved FDA additives, or distinctly low-quality matter at or above the defect action level.

FGIS' agreements with other USDA agencies, such as AMS (see part 4), ARS, and APHIS deal with research, studies, and other services. For example, FGIS has an agreement with USDA's Agricultural Stabilization and Conservation Service under which FGIS performs contamination tests on processed grain commodities for USDA's domestic and foreign donation programs. Another agreement between FGIS and ARS provides for cooperation in research to develop a new wheat classification system.

Critical Food Safety and Quality Issues Facing FGIS During the 1990s

According to FGIS, its critical food safety and quality issues of the 1990s include

- providing top-quality services,
- retraining the current work force to use new testing technology,
- taking action to help prevent mycotoxin- and pesticide residue-contaminated grains from entering the market, and
- growing concern for better quality assurance by importers and domestic buyers.

FGIS said that a primary concern is to provide top-quality service to fulfill its legislated responsibilities. Delivering such service depends on well-trained and dedicated people and FGIS' ability to use the appropriate technology in the national inspection system.

FGIS stated that use of new testing methodologies will require retraining the current work force, which relies heavily on human judgment in

making subjective quality analyses. This is a long-term process and offers the opportunity for FGIS to recruit and develop employees in underrepresented groups.

According to FGIS, new technology will enable FGIS to better measure grain quality in terms of intrinsic attributes as well as impurities and contaminants, such as mycotoxins and chemical residues. Providing this type of service will require further advances in quality control, an area that is receiving a great deal of attention within the agency. According to FGIS, it believes that as the ability to measure toxins and residues improves, the pressure for the national inspection system to have a direct role in regulating food safety will increase.

Also, FGIS senses a growing concern for better quality of grains and oil seeds by importers and domestic buyers. FGIS studies indicate that interest in specialized, intrinsic value, and end-use testing is growing.

National Marine Fisheries Service Activities Relating to Seafood Safety and Quality

The National Marine Fisheries Service, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, administers two programs dealing with food safety and quality activities—the voluntary National Seafood Inspection Program and the Product Safety, Quality and Identity Research Program.

Major Legislation

NMFS' food safety and quality activities are conducted pursuant to the laws discussed below.

Agricultural Marketing Act of 1946, Fish and Wildlife Act of 1956, and Reorganization Plan No. 4 of 1970

The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.), authorized the Secretary of Agriculture to establish a voluntary inspection and certification program for agricultural products, including fish and shellfish, in interstate commerce through services made available on a fee-for-service basis. The act also required the Secretary to, among other things, conduct research and development of methods of processing, packaging, handling, storing, and preserving products and develop and improve standards of quality, condition, quantity, grade, and packaging to encourage uniformity and consistency in commercial practices.

Pursuant to the Fish and Wildlife Act of 1956 (16 U.S.C. 742a et seq.), USDA's functions and authorities pertaining to commercial fisheries were transferred to the U.S. Department of the Interior in 1958. The transfer included the voluntary seafood inspection program. The act also authorized the Secretary of the Interior to improve production and marketing practices. Reorganization Plan No. 4 of 1970 transferred the functions described in the Fish and Wildlife Act of 1956, including the voluntary seafood inspection program, from the Department of the Interior to NOAA.

Lacey Act

The Lacey Act, as amended (16 U.S.C. 3371 et seq.), makes it unlawful to deliver, carry, transport, or ship by any means for commercial or noncommercial purposes or sell in interstate or foreign commerce any fish or wildlife that was taken, transported, or sold in violation of any federal, state, or foreign country's law or regulation.

Magnuson Fishery Conservation and Management Act

The Magnuson Fishery Conservation and Management Act, as amended (16 U.S.C. 1801 et seq.), requires fishery resources to be used to the greatest overall benefit to the nation, with specific reference to the use of the nation's fishery resources as food. The act includes a mandate for programmatic activities to, among other things, maximize the quality of seafood products to ensure the greatest economic return for harvested resources.

National Ocean Pollution Research and Development and Monitoring Planning Act

The National Ocean Pollution Research and Development and Monitoring Planning Act of 1978 (33 U.S.C. 1701 et seq.) requires NOAA to develop the necessary base of information to protect public health and provide for the rational, efficient, and equitable conservation and development of ocean and coastal resources.

Organizational Units and Responsibilities

NMFS' Office of Trade and Industry Services located at NMFS headquarters in Silver Spring, Maryland, supervises the Office's Inspection Services Division and the Utilization Research and Services Division. These divisions are primarily responsible for executing NMFS' two food safety and quality programs—the National Seafood Inspection Program and the Product Quality, Safety and Identity Research Program. The NMFS organizational units and their responsibilities under the two programs are discussed below.

National Seafood Inspection Program

The Inspection Services Division, Office of Trade and Industry Services, conducts the National Seafood Inspection Program—a voluntary, fee-based fish and shellfish products inspection and grading program. Division employees inspect and certify plants and seafood products and issue certification marks, including the Packed Under Federal Inspection mark and/or U.S. Grade A mark.

The Division has three major units: Technical Services, Field Operations, and the National Seafood Inspection Laboratory.

Technical Services Unit

The Technical Services Unit is responsible for

- training NMFS inspectors, cross-licensed USDA and state inspectors, and other interested parties;
- providing education and information services related to the inspection program;

- developing product grade standards and federal purchase specifications; and
- participating with international organizations in developing and implementing international standards and codes of practice.

Field Operations Unit

The Field Operations Unit conducts the program's day-to-day operations and services. The Unit's activities include

- vessel and plant sanitation inspections,
- product inspection and grading, and
- product certification according to established specifications and criteria.

The Unit has three inspection branches—the Northeast, in Gloucester, Massachusetts; the Southeast, in St. Petersburg, Florida; and the Western, in Bell, California. During fiscal year 1989, the branches maintained eight satellite inspection offices, as follows:

- Northeast Inspection Branch: Rockland, Maine; New Bedford, Massachusetts; and Hampton, Virginia.
- Southeast Inspection Branch: Miami and Tampa, Florida; and Brownsville, Texas.
- Western Inspection Branch: Seattle and Bellingham, Washington.

National Seafood Inspection Laboratory

The National Seafood Inspection Laboratory in Pascagoula, Mississippi, provides a variety of support services to the inspection program, such as

- performing laboratory analyses,
- executing various scientific research projects and new testing procedures, and
- reviewing and approving labels and product specifications submitted by program participants to comply with applicable federal requirements.

The Laboratory also prepares the semiannual "USDC Approved List of Fish Establishments and Products" and the quarterly "Inspection Connection" and mails them to all inspectors, program participants, buyers, and other interested parties.

Product Safety, Quality and Identity Research Program

The Utilization Research and Industry Services Division, Office of Trade and Industry Services, provides national coordination, oversight, and evaluation of the Product Safety, Quality and Identity Research Program. Program activities are carried out at three NMFS facilities:

Charleston Laboratory in Charleston, South Carolina; Utilization Research Division in Seattle, Washington; and Gloucester Laboratory in Gloucester, Massachusetts.

The program provides services and information on impediments to the full utilization of fishery resources. Activities include the collection, interpretation, publication, and dissemination of information and research results to facilitate optimum use of living marine resources.

Safety research includes activities that address the continuing concern about the impact of environmentally and process-induced contamination of seafood on consumers and the fishing industry. NMFS' quality research efforts are directed to improving the overall quality of U.S. seafood marketed domestically and internationally.

Program Activities

NMFS' food safety and quality activities relating to the National Seafood Inspection Program and the Product Safety, Quality and Identity Research Program are discussed below.

National Seafood Inspection Program Activities

The following range of activities is performed by Inspection Services Division personnel for any financially interested party, including harvester, processor, food-service distributor, importer, and exporter:

- Vessel and plant sanitation inspection. NMFS inspects seafood in accordance with the plant sanitation requirements established by FDA and with Federal Standard 369, Sanitation Standards for Fish Plants.
- Product evaluation. NMFS can evaluate products in a processing facility or a warehouse and can include evaluation for general condition, wholesomeness, proper labeling, and conformance with U.S. Standards for Grades. In-plant evaluation of products during processing allows the use of the Packed Under Federal Inspection and/or the U.S. Grade A marks on the product label.
- Product specification and label review. Plants contracted for in-plant inspection service submit product specifications and labels for NMFS review and approval before use. NMFS reviews seafood for conformance to FDA's labeling requirements and proper use of food additives and the inspection marks. This service is also available to nonparticipants as a consultative service on a fee-for-service basis.
- Laboratory analyses. These analyses include microbiological tests, analyses for chemical contaminants, index of decomposition, and species identification.

- Training. Training is available and has been provided to Department of Defense quality assurance auditors and food inspectors, retailers, food-service and plant personnel, and other interested parties. Subjects include sanitation and employee hygienic practices, product evaluation and grading, regulations, and preferred handling practices.
- Education/information. This activity may be in the form of presentations at scheduled events and through materials exhibits, publications, press kits, and technical advice as requested by industry, consumers, government agencies, fisheries trade associations, academia, retail, food-service groups, and the media.

Another Inspection Services Division activity, although not considered a direct part of the inspection service, is the development and/or amendment of U.S. standards for grades and specifications. Appropriations fund this activity.

NMFS activities and inspection data under the National Seafood Inspection Program are discussed below under the following captions: import activities, export activities, establishments subject to inspection, dollar value of food products subject to inspection, inspection data for 1981-89, dollar value of food products subject to inspection, relationship to state inspection programs, laboratory test data, and compliance activities.

Import Activities

The Federal Food, Drug, and Cosmetic Act requires that imported seafood products meet the basic requirements imposed on comparable items produced by U.S. processors for interstate commerce. All imports of seafood products are subject to FDA sampling, inspection, and analysis at the port of entry. FDA port-of-entry inspection determines whether products meet existing requirements regarding wholesomeness, labeling, tolerances for pesticide residues, and food additives.

Most imported fishery products that NMFS lot[1] inspects upon request are inspected for compliance with buyer specifications, after FDA accepts the products into the United States. NMFS performs analyses for microorganisms, species identification, and chemical additives when there is a suspicion of noncompliance or at the request of the requesting party.

NMFS' lot inspection certificate is the official document used for import and domestic lot inspection certification. Since import and domestic lot

[1]"Lot" generally means a pile of similar containers containing a similar type of processed product which is separated or marked differently from other piles in the same warehouse.

inspections are not segregated, the volume of lot-inspected imported seafood is not known.

Import and export inspection services can be provided by any NMFS or NMFS cross-licensed inspector at any of its offices, the port of entry, or a designated warehouse. As of January 1990, there were 144 NMFS inspectors, 63 NMFS cross-licensed federal (USDA) inspectors, and 74 NMFS cross-licensed state inspectors. There are 10 NMFS lot inspection offices, 10 NMFS cross-licensed state lot inspection offices, and 4 NMFS cross-licensed USDA lot inspection offices.

Export Activities

NMFS conducts inspection and analyses of fishery commodities for export and issues official U.S. government certificates attesting to the findings. Certification for compliance of exported products can be provided for foreign requirements, where known, or on the basis of specifications set by the exporter.

Table 6.1 shows the number of export inspection certificates issued for 1984 through 1989. They represent the minimum number of inspections, since the certificates often represent more than one inspection.

Table 6.1: NMFS Export Inspection Certificates Issued, Calendar Years 1984-89

Year	Export inspection certificates issued
1984	1,916
1985	1,930
1986	2,714
1987	4,217
1988	4,283
1989	2,469
Total	**17,529**

Source: NMFS

Establishments Subject to Inspection

According to "Fisheries of the United States, 1988," there were 1,878 processing plants in 1987. Of those plants, an average of 141 plants (about 7.5 percent) were contracted for NMFS inspection services that year. This figure does not reflect the number of inspections performed on a noncontract basis (e.g., lot inspections).

Inspection Data for 1981-89

Table 6.2 shows the pounds of domestic and imported fishery products inspected for 1981 through 1989, classified by type of inspection.

Table 6.2: NMFS-Inspected Fishery Products, Calendar Years 1981-89

Pounds in millions

	In-plant			Lot		
Year	Grade A	PUFI[a]	No Mark	Domestic	Export	Total
1981	110	366	43	49	56	**625**
1982	95	305	64	41	64	**569**
1983	92	315	64	41	54	**567**
1984	100	244	59	34	47	**484**
1985	118	193	47	40	44	**443**
1986	128	192	38	41	44	**442**
1987	113	199	33	33	54	**433**
1988	106	198	58	40	93	**495**
1989	117	190	81	60	114	**563**

[a]Placed Under Federal Inspection

Source: NMFS

Dollar Value of Food Products Subject to Inspection

No data are available on the value of food products that were inspected by the National Seafood Inspection Program. However, table 6.3 shows data on the value of domestic and imported edible processed fishery products for 1980 through 1988.

Table 6.3: Value of Edible Processed Fishery Products, Calendar Years 1980-88

Dollars in millions

Year	Fresh/frozen	Canned	Cured	Total
1980	$2,110	$1,804	$125	$4,039
1981	2,527	1,878	135	4,540
1982	2,521	1,325	143	3,988
1983	3,124	1,394	159	4,677
1984	3,234	1,436	165	4,835
1985	3,257	1,302	168	4,727
1986	3,481	1,395	110	4,986
1987	4,041	1,476	136	5,654
1988	3,562	1,385	94	5,040

Source: NMFS

Relationship to State Inspection Programs

Generally, NMFS' interaction with state inspection programs is through cooperative agreements relative to voluntary inspection services for fish and fishery products. Under the agreements, NMFS provides training to state inspectors who are certified to perform NMFS inspection activities and monitors state inspection activities through interaction with the states' managing offices. NMFS does not provide federal grants to states for providing inspection services on behalf of NMFS. Rather, it reimburses the states for their costs, at an agreed-upon hourly rate. As of

May 1990, NMFS had agreements with the following 12 states: Alabama, Alaska, Arkansas, Florida, Louisiana, Minnesota, Mississippi, New Jersey, New York, Oregon, Tennessee, and Washington.

Laboratory Test Data

Table 6.4 shows the number and type of laboratory tests conducted at the National Seafood Inspection Laboratory for fiscal years 1981 through 1989, classified by type of test—microbiological, chemical, and physical.

Table 6.4: NMFS Laboratory Tests, Fiscal Years 1981-89

Year	Microbiological	Chemical	Physical	Total
1981	75	35	5	**115**
1982	69	28	7	**104**
1983	70	6	2	**78**
1984	71	7	6	**84**
1985	39	9	11	**59**
1986	43	23	5	**71**
1987	51	20	14	**85**
1988	68	22	15	**105**
1989	33	25	8	**66**

Source: NMFS

Compliance Activities

Compliance activities for participants in the voluntary seafood inspection program would include, for example, determining a plant's compliance with sanitation standards. In cases of noncompliance, NMFS notifies appropriate plant personnel to take corrective action. If continued noncompliance occurs, NMFS suspends services. Because of the program's voluntary nature, formal suspension is seldom required; the noncomplying plant withdraws from the program of its own accord. When conditions at a plant are such that a potential safety or health concern exists, NMFS contacts the appropriate state agency and/or FDA to follow up on items that are unresolved.

Because of the program's voluntary and quality-oriented nature, the most common reason for NMFS to take formal suspension action is the result of nonpayment of inspection services. In fiscal year 1988, five plants were suspended—four for nonpayment and one for continued sanitation noncompliance. In fiscal year 1989, four plants were suspended, all for nonpayment.

Product Safety, Quality and Identity Research Program Activities

NMFS carries out the following types of food safety and quality activities under its Product Safety, Quality and Identity Research Program:

- Seafood safety research. This research produces, collects, interprets, and disseminates information on the identity, level, toxicology, risk, and public health significance of hazardous environmental contaminants found in seafoods. These include natural biotoxins, heavy metals, petroleum hydrocarbons, synthetic organic chemicals, viruses, fungi, and bacteria. The information is used to design and/or improve existing seafood inspection, industry quality control, and fishery management programs to protect consumers from seafood hazards and the industry from unwarranted adverse publicity and perception problems.
- Microbiological safety research. This research's purpose is to increase the safety and marketability of fishery products by identifying the hazards and critical control points of processing and storage in relation to growth of food-poisoning organisms and to develop process parameters for inhibiting or destroying Clostridium botulinum and Listeria monocytogenes, the causative agents of the diseases botulism and listeriosis, respectively.
- Molluscan shellfish research. This research produces, collects, interprets, and disseminates information on the identity, level, risk, and public health significance of hazardous microbial (viruses, bacteria, and fungi) contaminants found in molluscan shellfish. The information is used to design and/or improve existing shellfish purification technologies, shellfish inspection, industry quality control, and fishery management programs.
- Fishery chemistry research. This research includes development of species identification methodology on the basis of biochemical and immunological techniques. Studies are done on the (1) nature of textural change in frozen fish; (2) effects of handling, storage, and processing on the quality of seafoods; (3) development of nutritional data relating to fresh and processed seafoods; (4) analyses of samples of food fish for organic contaminants; and (5) development of a new methodology for microcontaminant analysis.
- Fishery technology research. This research includes technology transfer for fishery development programs and the application of technological advances to the quality assurance of fresh and frozen seafoods.
- Underutilized species research. This research is conducted on use concepts, preservation, and quality assurance of underutilized species. It addresses quality; composition; preservation; handling; processing safety; and nutritional, functional, and edibility characteristics of species of fish that are not currently utilized because of marketing impediments.

- Biomedical test materials program. This program produces fish oil test materials which are provided to researchers approved by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration to conduct long-term clinical studies, basic biochemical investigations, and animal-feeding studies necessary to determine the nutritive, therapeutic, and preventative effects of omega-3 fatty acids of marine origin.
- Oil-tainted fish. This initiative focuses on addressing the issues associated with preventing the marketing of oil-tainted fish that resulted from the Alaska oil spill.
- Input to Codex Alimentarius. NMFS provides coordination and technical input for U.S. participation in Codex, which develops (1) international technical standards of minimum quality and identity for fish and fishery products and (2) codes of hygienic and technological practice.
- Technical support to law enforcement personnel. Law enforcement personnel sometimes need technical support while pursuing threatened and endangered species and fishery management law violations as well as state game fish violations. An example of technical support provided includes verifying the causes of death of marine mammals suspected of dying from ingestion of fin fish containing naturally occurring biotoxins. Since these finfish can also be used for food, the implications of these biotoxins to human risk is also of concern.
- Extramural research and development. Extramural research and development activities are achieved through cooperative agreements. A portion of this effort focuses on seafood safety, quality, and identity tasks that complement the NMFS in-house research program.

Funding Levels

NMFS' food safety and quality activities are funded through a combination of appropriated funds and user fees (reimbursable costs). Federal appropriations generally fund the Product Safety, Quality and Identity Research Program and the standards, specifications, and laboratory services provided under the National Seafood Inspection Program. User fees generally fund the inspection and grading services provided under the National Seafood Inspection Program. Table 6.5 shows the appropriated funds and reimbursable costs for the two programs.

Table 6.5: Funding of NMFS Food Safety and Quality Activities, Fiscal Years 1988-89

Dollars in thousands

	Appropriated		Reimbursable	
Activity	**1988**	**1989**	**1988**	**1989**
Inspection program				
Inspection/grading	$0	$0	$4,402	$5,096
Standards/specifications	173	190	0	0
Laboratory	714	706	0	0
Subtotal	**887**	**896**	**4,402**	**5,096**
Research program				
Charleston Laboratory	3,683	3,020	0	0
Seattle Laboratory	1,173	1,381	0	0
Gloucester Laboratory	1,006	980	0	0
Headquarters	303	253	0	0
Subtotal	**6,165**	**5,634**	**0**	**0**
Total	$7,052	$6,530	$4,402	$5,096

Source: NMFS

For fiscal year 1988, the two programs' costs totaled about $11.5 million, of which about 62 percent was funded by federal appropriations and about 38 percent by user fees. Federal appropriations funded all of the research program and 17 percent of the inspection program costs.

For fiscal year 1989, the programs' costs totaled about $11.6 million, of which about 56 percent was funded by federal appropriations and about 44 percent by user fees. Federal appropriations funded all of the research program and 15 percent of the inspection program costs.

Staffing Levels

Table 6.6 shows the staffing levels for the two programs for fiscal years 1988 and 1989.

Table 6.6: Staffing Levels for NMFS' Food Safety and Quality Activities, Fiscal Years 1988-89

	Staffing-level	
Program/organizational unit	**1988**	**1989**
Inspection Program		
Headquarters	6	7
Northeast Inspection Branch	45	46
Southeast Inspection Branch	33	31
Western Inspection Branch	37	39
Technical Services Unit	5	5
National Seafood Inspection Laboratory	31	35
Subtotal	**162**	**163**
Research Program		
Charleston Laboratory	47	51
Seattle Laboratory	25	22
Gloucester Laboratory	23	23
Headquarters	7	6
Subtotal	**102**	**102**
Total	264	265

Source: NMFS

Coordination With Other Federal Agencies

During fiscal year 1989, NMFS had seven written cooperative agreements or memorandums of understanding with other federal agencies—four with USDA, three with FDA, and one with the Defense Logistics Agency—to coordinate its food safety and quality activities. The general substance of each agreement is described below.

One of the four agreements with USDA establishes NMFS and USDA responsibilities relating to the research and development of standardization documents for fishery products purchased by federal agencies. The other three provide for cross-licensing employees of the two agencies to perform inspection and certification services pursuant to the Agricultural Marketing Act of 1946. Under the act, NMFS and USDA perform similar inspection and certification services on behalf of the other agency—using cross-licensed inspectors—for industry applicants on a fee-for-service basis for fishery and agricultural products.

One memorandum of understanding with FDA covers fishery products plants that are under NMFS voluntary inspection contracts and also subject to FDA inspection. The agreement is described in part 1. Another NMFS memorandum of understanding with FDA relates to research programs for fishery products. The agreement's purpose is to improve and

increase the cooperation/coordination of research efforts, avoid duplication of effort, and make more efficient use of federal resources supporting fishery products research programs that are of joint interest to the two agencies. Research areas included in the agreement cover activities of mutual concern related to the safety, quality, nutrition and labeling requirements for fish and shellfish products. Meetings have been held semiannually since 1981 to (1) focus and prioritize the needs for continuing research, (2) plan research projects for joint execution, and (3) share results of completed research.

NMFS' other memorandum of understanding with FDA concerns the enforcement of laws against illegal commerce in molluscan shellfish. NMFS advises FDA when investigations reveal illegal shellfish harvesting that would endanger public health by harvesting shellfish from polluted waters. Both NMFS and FDA coordinate their activities under the memorandum of understanding with the public health and fisheries agencies of interested and affected states.

NMFS' memorandum of understanding with the Defense Logistics Agency authorizes NMFS to inspect and certify fish and fishery products purchased by the Defense Logistics Agency for compliance with quality assurance requirements in published standards and contract specifications.

Critical Food Safety and Quality Issues Facing NMFS During the 1990s

According to NMFS, potential consumer hazards in seafoods can be classified into three categories: product safety, plant and food hygiene, and economic fraud. Causative agents of public hazards in seafood are either environmental (natural or manmade), process, or distribution induced. NMFS stated that it faces the following critical food safety and quality issues:

- Pollutants and contaminants.
- Biotoxins in finfish and molluscan shellfish.
- Cleansing of contaminated molluscan shellfish.
- Potential hazards associated with new processing, packaging, and marketing techniques.
- Decomposition indicators and international acceptance.
- Economic fraud.
- Equivalence of food control systems.
- Seafood inspection.
- Water conservation and reuse.

Pollutants and Contaminants

Fish and shellfish accumulate varying degrees of pollutants, petroleum hydrocarbons, and synthetic organic compounds (e.g., pesticides) that enter the environment through agricultural and industrial activities and disposal of wastes. These pollutants affect animal health and fishery resources' ability to reproduce, and enter into human food supplies. Seafoods—shellfish in particular—may also harbor pathogenic bacteria and viruses originating largely from human and animal waste at levels that can cause illness to consumers. According to NMFS, the impact of these contaminants will increase dramatically as the human population on the coasts continues to grow faster than waste/run-off management can be implemented.

Pollution of coastal and offshore fishing grounds has resulted in intermittent closures of some areas to both finfish and shellfish harvesting. NMFS believes that without long-term planning for control in concert with coastal states, the nation's fish stocks are being jeopardized. The safety of consuming fish from these areas or marginally contaminated waters is not well understood. The likelihood of human exposure to these pollutants depends on their physical, chemical, and biological form; concentration; and persistence or survival. The character and nature of environmental pathways leading to human exposure are also important variables.

Biotoxins in Finfish and Molluscan Shellfish

Toxins in finfish and molluscan shellfish (clams, oysters, mussels, and scallops) have increasingly been implicated in human health disorders. According to the Centers for Disease Control's records for 1983-87, ciguatera and scombroid poisoning were the first and second most frequently reported illnesses associated with eating fish. In addition to consumer safety issues, toxins pose a severe economic threat to the shellfish industry.

The significance of other toxins (domoic acid, paralytic shellfish poisoning, and diuretic shellfish poisoning) and toxin presence and bloom evolution require investigation of the dynamics of toxin uptake, discharge, and/or removal by individual species. Detection methodology appropriate to industry needs also requires development. Research results and technology must be transferred to the industry to facilitate resource access and use. In addition, monitoring is required to prevent contaminated products from being introduced into the market.

Cleansing of Contaminated Molluscan Shellfish

NMFS said that the depuration (cleansing) process, as currently practiced, may not be an effective technology in eliminating all viral agents from molluscan shellfish in a timely manner. Certain viral agents show distinctly different and prolonged elimination rates in shellfish relative to bacterial indicators. According to NMFS, critical information is missing about the depuration of viral agents in shellfish, and controlled studies have been hindered by a lack of methods to enumerate these particles in shellfish. In addition, there is a paucity of information on the elimination of chemical contaminants from shellfish. Limited studies addressing heavy metals elimination rates indicate that metals remain high in depurating products for extended months.

Potential Hazards Associated With New Processing, Packaging, and Marketing Techniques

NMFS stated that considerable data are available on older, "time-tested" methods of processing and marketing fishery products. However, increased consumer interest in fishery products and foreign trade opportunities have inspired altering these methods, introducing new processing techniques, and developing new value-added products. Many of these procedures inactivate the normal spoilage flora, which in turn increases the products' shelf-life.

NMFS stated that new food processing and packaging technology may have a profound effect on safety and quality. Food processing, irradiation, shellfish depuration, innovative product treatments and additives, manufacturing imitation seafoods, vacuum and modified-atmosphere packaging, and home use of microwave food preparation are some items sure to receive increased continued review by public health agencies.

According to NMFS, unless adequate processing procedures are followed and/or inhibitors of bacterial pathogens are present in the fishery product, potential hazards can develop during distribution or at the consumer level through food poisoning outbreaks, causing illnesses and occasionally death. A baseline of knowledge on new processing, packaging, and marketing strategies and the potential risks introduced requires investigation and consensus among food control authorities on a list of priority research that should be undertaken.

Decomposition Indicators and International Acceptance

Seafood decomposition action levels, which result in rejection or detention during inspections, are not available for many seafoods domestically and are not internationally uniform. NMFS said that a need exists to reassess current decomposition action levels, develop new ones where

they are absent, and align them with international indexes of minimum quality for consumer protection and trade purposes.

Economic Fraud

Economic fraud is the intentional or unintentional misrepresentation of a product as a higher value item than it truly is. Examples of economic fraud include species substitution, overbreading of breaded seafoods, and short net weights of frozen products sometimes caused by including the weight of the protective coating of ice as part of the net weight. NMFS believes that these practices can be eliminated by developing an effective monitoring and compliance system for each commodity.

Equivalence of Food Control Systems

NMFS stated that public health and safety problems related to seafood consumption are complicated by the fact that over 60 percent of total U.S. seafood consumption is of seafood imported from over 125 countries. NMFS believes that better assessment and control of consumer hazards in overseas processing and products need to be addressed in any future seafood regulation program. Such controls may be accomplished by providing assistance to countries in developing food control systems that are determined to provide public health and safety protection equivalent to the U.S. system. According to NMFS, flexibility and capacity to address these different needs and controls will need to be built into legislation that addresses mandatory seafood inspection.

Seafood Inspection

NMFS said that a major factor affecting seafood safety and quality is the inspectional approach to food system control. Plant hygiene (sanitation) and food hygiene (wholesomeness) are directly related to operational and food-handling practices from fishery harvest through processing and distribution. For the large part, the food industry has been dependent on outdated control concepts, such as continual on-site inspection (used for meat and poultry) and duplicative federal, state, and local regulation and enforcement activities.

NMFS believes that under the Hazard Analysis Critical Control Point approach recommended in 1985 by the National Academy of Sciences, the industry must take the lead to define each operational step of a processing operation, indicate the hazard and relative importance of each step, identify the critical control points for the significant hazards, define preventive measures to minimize the hazard, and detail the monitoring procedures (observation or measurement) that can be used for

compliance procedures. Each step in the food flow system can be defined, and decisions on reasonable and effective controls can be made.

NOAA's Model Seafood Surveillance Project is conducting workshops on a commodity-by-commodity basis. Workshop participants examine the hazards associated with their products' end use and develop a food control model, on the basis of the Hazard Analysis Critical Control Point approach, applicable to their industry.

After such an industry-driven system is developed, regulatory authorities have the opportunity to assess the appropriateness of selected critical control points, monitoring procedures, record-keeping requirements, and corrective action to verify that the system is effective in eliminating public health and safety hazards.

Water Conservation and Reuse

Adequate water of acceptable quality is often a critical item in seafood-processing facilities. NMFS believes that clean-up measures to ensure that recycled water is safe and suitable for food contact are essential to control contamination and the spread of foodborne illness agents.

Other Selected Federal Agencies Involved With Food Safety and Quality Activities

In addition to the six principal federal agencies discussed in parts 1 through 6 of this report, a number of other federal agencies carry out food safety and quality activities. In this section, the following agencies' food safety and quality activities are discussed briefly:

- Agricultural Research Service, USDA;
- Animal and Plant Health Inspection Service, USDA;
- Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury;
- Centers for Disease Control (CDC), Public Health Service, Department of Health and Human Services;
- Federal Trade Commission (FTC); and
- United States Customs Service, Department of the Treasury.

For these agencies, information similar to that for the six principal agencies is presented, but in less detail. Also, we gave each agency the option to provide information on what they considered to be the critical food safety and quality issues of the 1990s. Three of the six agencies—ARS, APHIS, and CDC—chose to provide information on issues.

Agricultural Research Service

ARS' mission is to develop new knowledge and technology which will help ensure an abundance of high-quality agricultural commodities and products at reasonable prices to meet the increasing needs of an expanding economy and to provide for the continued improvement in the standard of living of all Americans.

Major Legislation

ARS carries out food safety and quality research activities pursuant to the Department of Agriculture Organic Act of 1862 (7 U.S.C. 2201 et seq.); the Research and Marketing Act of 1946, as amended (7 U.S.C. 427 et seq.); and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3101 et seq.).

Organization and Responsibilities

ARS' headquarters is located in the Washington, D.C., area. Its field activities are managed through 8 area offices and are carried out at 126 separate field locations.

ARS is responsible for conducting a wide range of research relating to USDA's mission, including research to assure food safety and quality for the nation's consumers. Much of ARS' food safety and quality activities are performed at the following ARS research laboratories and centers:

- Beltsville Agricultural Research Center, Beltsville, Maryland.
- Eastern Regional Research Center, Philadelphia, Pennsylvania.
- Meat Animal Research Center, Clay Center, Nebraska.
- National Animal Disease Center, Ames, Iowa.
- National Peanut Research Laboratory, Dawson, Georgia.
- Northern Regional Research Center, Peoria, Illinois.
- Poisonous Plants Research Center, Logan, Utah.
- Richard Russell Research Center, Athens, Georgia.
- Southern Regional Research Center, New Orleans, Louisiana.
- Food Animal Protection Research Laboratory, College Station, Texas.
- Western Regional Research Center, Albany, California.

Program Activities

ARS' food safety and quality activities include the following:

- Developing methodologies to detect and control bacterial and parasitic contamination of meat and poultry and their products, including the control of salmonella and campylobacter in live animals.
- Developing methodologies to identify and detect chemical residues (of drug, pesticide, or fungal origin) of concern in meat and poultry and their products, including the development of pharmacokinetic models of drug metabolism in food animals.
- Developing methodologies to detect mycotoxins in plant commodities and to prevent mycotoxin infestation in the field.

Funding and Staffing Levels

During fiscal year 1989, ARS had about $606 million available for its programs and used about $25.2 million (about 4 percent) for food safety and quality activities.

As of September 30, 1989, ARS had a total of 6,947 full-time employees and 1,624 other than full-time employees. Of the total, 453 (about 7 percent) of the full-time employees and 30 (about 2 percent) of the part-time employees worked in central offices in the Washington, D.C., area.

During fiscal year 1989, ARS used about 168 scientists years on food safety and quality activities.

Coordination With Other Federal Agencies

Within USDA, ARS coordinates its food safety research with the Food Safety and Inspection Service, the Federal Grain Inspection Service, and the Agricultural Marketing Service. ARS also coordinates its research

with other federal agencies, primarily EPA and FDA. ARS achieves its coordination through a combination of formal memorandums of understanding, designated formal liaisons, informal working relationships, and joint workshops.

Critical Food Safety and Quality Issues of the 1990s

ARS provided the following list of items it believes will be critical food safety and quality issues of the 1990s:

- Development of control methods for bacteria such as salmonella and campylobacter in meat and poultry products.
- Development of control methods for hazardous bacteria in combination meat and vegetable products.
- Development of technology to detect and reduce chemical pesticide use.
- Control of aflatoxin and other mycotoxins in field crops and tree nuts.
- Control of both hazardous microorganisms and residues to meet the needs of export.

Animal and Plant Health Inspection Service

APHIS' mission is to provide leadership in ensuring the health and care of animals and plants, to improve agricultural productivity and competitiveness, and to contribute to the national economy and the public health.

Major Legislation

APHIS stated that it has not had legal responsibilities to protect or promote food safety and quality. According to APHIS, it has no statutory authority to perform food safety activities unless the organism or chemical of concern to public health is also of concern to animal or plant health. However, APHIS added that certain APHIS animal health programs do affect food safety. Programs designed to protect the animal industry against pathogens or diseases that can pose foodborne risk to humans also improve food safety. For example, during 1990, APHIS had an emergency program in operation against salmonella enteritidis in poultry. Under the program, APHIS tests and monitors all egg-type breeding and multiplier flocks, as well as controls the interstate movement of poultry, eggs, and material from known culture-positive flocks and exposed flocks.

Also, APHIS stated that certain of its plant health programs indirectly affect food safety. Chemicals and natural toxins are primary food safety concerns for plant-food commodities. APHIS programs leading to reduced

chemical applications, such as Integrated Pest Management or biological control strategies, reduce pesticide use.

Organization and Responsibilities

APHIS headquarters is located in the Washington, D.C., area. During fiscal year 1989, field activities were carried out by 10 regional offices and 119 field offices. Much of APHIS' work is conducted in cooperation with state and local agencies, private groups, and foreign governments.

In the field, APHIS maintains an infrastructure of animal and plant health specialists throughout the United States who deal with producers and are responsible for addressing animal and plant health mandates.

APHIS stated that its animal and plant health programs aim to protect the health of animal and plant resources. It added that although its current programs are not designed to directly address food safety objectives, it could become more active in addressing these issues in the future. APHIS stated that it recognizes that effective food safety protection must begin on the farm—at the beginning of the food production process. It said that producers must accept responsibility and accountability for their products prior to their entry into, and subsequent movement through, the market chain.

APHIS also stated that its field infrastructure might support a future APHIS role of assisting producers in developing production practices and monitoring systems for food commodities, including disease prevention strategies consistent with food safety objectives.

Program Activities

APHIS carries out its mission, in part, by performing the following types of activities:

- Plant disease and pest control. In cooperation with states, APHIS carries out surveys to detect harmful pests and diseases, inspections to prevent the spread of plant pests to noninfested areas of the country, and programs to eradicate new or established plant pests and diseases. APHIS conducts an inspection program at ports of entry to prevent the introduction of foreign plants and animal pests and disease which are harmful to agriculture in the United States. APHIS also certifies plants and plant products for export and regulates imports and exports of endangered plant species.
- Animal disease and pest control. In cooperation with states, APHIS conducts programs to (1) prevent communicable diseases of foreign origin

from entering the United States; (2) diagnose foreign animal diseases, should they enter the country; and (3) prevent the spread of diseases through interstate shipments of livestock or distribution of impure, unsafe, impotent, and nonefficacious veterinary biologics. APHIS conducts other programs to control and eradicate livestock diseases present in the United States.

Funding and Staffing Levels

APHIS stated that although many of its programs indirectly affect food safety, total APHIS funding and staffing level data for these programs are inaccurate measures of its "food safety resources."

The total amount available to APHIS for fiscal year 1989 was about $369 million, including about $341 million of appropriated funds and about $28 million in reimbursements.

As of September 30, 1989, APHIS had 4,873 permanent full-time employees and 1,019 part-time employees. Of the total, 725 (about 15 percent) of the full-time employees and 85 (about 8 percent) of the part-time employees worked in central offices in the Washington, D.C., area.

Coordination With Other Federal Agencies

In the area of animal health, APHIS cooperates with and responds to reports from USDA's Food Safety and Inspection Service, FDA, and the Centers for Disease Control by conducting epidemiological tracebacks for salmonella enteritidis and related activities. In addition, APHIS occasionally assists in investigating for chemical residues in food animals when states or other federal agencies request it. Also, APHIS has assisted FDA in the area of plant health by monitoring plant-food import commodities for chemical residues.

Critical Food Safety and Quality Issues of the 1990s

APHIS provided the following list of items it believes will be critical food safety and quality issues of the 1990s:

- Microbiological foodborne contamination, especially in populations at risk such as fetuses, the elderly, and immunosuppressed persons, including AIDS patients and chemotherapy patients.
- Public perceptions of food safety, including improving the communication of risks to the public and media, responding to publicized food safety concerns of consumer groups and others, and dealing with potential effects of consumer perceptions of food safety on the economic health of the agricultural industry.

- Tools for food safety policy-making in government agencies, including increasing federal emphasis on risk assessment and risk management, focusing on the food safety process rather than the safety of food products, developing microbiological criteria, and stressing the importance of uniform national standards for food safety tolerance levels.
- Tools for improved implementation of food safety policies, such as developing more rapid, reliable tests to monitor microbiological and chemical contaminants.
- Ante- and post-mortem food inspection activities for additional species of animals (e.g., rabbits and fish), such as those performed by FSIS for cattle, swine, sheep, goats, and poultry.

Bureau of Alcohol, Tobacco and Firearms

ATF is responsible for administering and enforcing laws relating to firearms and explosives, as well as those covering the production, use, and distribution of alcohol and tobacco products.

Major Legislation

ATF stated that the two primary laws it administers and enforces relating to alcoholic beverages are the Federal Alcohol Administration Act (27 U.S.C. 201, et seq.) and the Internal Revenue Code relating to distilled spirits, wines, and beer.

The Federal Alcohol Administration Act

- gives ATF authority to issue regulations regarding the labeling and advertising of alcoholic beverages to ensure that they provide the consumer with adequate information concerning product identity and quality;
- authorizes ATF to issue permits to allow firms to engage in the production, importation, or wholesale distribution of alcoholic beverages;
- gives ATF the authority to revoke or suspend a permit for willful violation of regulations issued under the act; and
- prohibits selling or shipping in interstate or foreign commerce distilled spirits, wines, or malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity with regulations prescribed by the Secretary of the Treasury.

The Internal Revenue Code gives ATF authority to detain any container that is in violation of the law (26 U.S.C. 5311) and also gives ATF seizure and forfeiture authority (26 U.S.C. 7302).

These two laws provide a comprehensive system of control over the production and distribution of alcoholic beverages, including on-site inspections, and procedures that require the advance approval of statements of processes, of formulas showing each ingredient to be used in the product, and all labels.

ATF stated that it has very limited statutory responsibility relating to the safety of alcoholic beverages. It said that the laws it administers do not address the safety of alcoholic beverages and do not give ATF any specific responsibilities in this area. However, ATF added that, for about the past 50 years, ATF and its predecessor agencies have exercised considerable control over the safety of alcoholic beverages through these and other federal laws and through agreements with other federal agencies. In addition, the Alcoholic Beverage Labeling Act of 1988 (27 U.S.C. 213 et seq.) requires a health warning statement on the labels of all alcoholic beverages bottled after November 17, 1989.

Organization and Responsibilities

ATF headquarters is located in Washington, D.C., but most of its personnel are stationed throughout the United States, where many of its operational functions are performed.

ATF has no operational segments exclusively devoted to the safety of alcoholic beverages. In fiscal year 1989, safety activities were conducted, in addition to all other field enforcement activities, by approximately 430 inspectors in 39 area offices and 5 regional offices.

ATF's Industry Compliance Division is responsible for oversight of activities relating to laboratory analysis of alcoholic beverages, identification of adulterants in alcoholic beverages, recall notices, and the conduct of recalls. ATF operates two alcohol laboratories located in Rockville, Maryland, and in Walnut Creek, California.

Program Activities

Regarding food safety, ATF's policy is that the American consumer should be protected from hazards associated with exposure to contaminated or mislabeled alcoholic beverages. ATF informed us that its major activities include

- establishing standards of identity, including regulations that prescribe ingredients, alcoholic strength, formula requirements, and manufacturing processes for most wines and distilled spirits;

- approving formulas for alcoholic beverages prior to their production or importation, which permits ATF to examine the formula and product for the presence of injurious or prohibited ingredients;
- sampling alcoholic beverages at production, wholesale, and retail levels to ensure product integrity and to examine for the presence of injurious or prohibited ingredients;
- requesting voluntary recalls of alcoholic beverages that are improperly labeled, that contain ingredients not approved for food use, that contain ingredients in excess of regulatory limitations, or that are not produced in accordance with approved formulas; and
- enforcing the Alcoholic Beverage Labeling Act of 1988.

Enforcement Activities

ATF has notified permit holders that it will consider suspending or revoking permits of persons who knowingly sell mislabeled alcoholic beverages, i.e., beverages that are not in conformity with standards of identity, not in conformity with formula, or containing prohibited ingredients.

ATF can use detention to prevent the sale or removal of an adulterated or mislabeled alcoholic beverage until permanent disposition is arranged or until a problem such as mislabeling is corrected.

Coordination With Other Federal Agencies

ATF coordinates its alcohol activities with FDA and the United States Customs Service.

FDA has responsibility for the safety of alcoholic beverages under FFDCA. However, because of ATF's long regulatory experience with the alcoholic beverage industry, ATF and FDA signed a memorandum of understanding in November 1987 which clarifies and delineates the enforcement responsibilities of each agency relating to the identification, testing, and recall of alcoholic beverages considered adulterated under FFDCA.

Under the agreement, ATF became the primary federal agency responsible for the safety of alcoholic beverages. The following are some provisions of the agreement:

- ATF will, in consultation with FDA, initiate rulemaking to require the label disclosure of ingredients identified by FDA as posing a potential health risk.

- ATF will test alcoholic beverages to determine the extent of adulteration problems.
- ATF will have primary responsibility for requesting firms to conduct voluntary recalls of alcoholic beverages found to be adulterated under FFDCA, after consulting with FDA, and for monitoring recalls.
- ATF will develop guidelines for identifying adulterated alcoholic beverages and for implementing voluntary product recalls.
- FDA will provide ATF, upon request, with a health hazard evaluation with respect to any substance found in alcoholic beverages.
- FDA will contact ATF when it learns or is advised that an alcoholic beverage is or may be adulterated.
- FDA and ATF laboratories will exchange information concerning methodologies and techniques for testing alcoholic beverages.

ATF coordinates with the United States Customs Service to prevent the entry of adulterated alcoholic beverages by identifying locations where contaminated alcoholic beverages are likely to enter the United States. ATF also may request Customs' assistance in determining whether it is necessary to detain contaminated products, to require proof that the products are not contaminated before entry, or to take other appropriate action.

Centers for Disease Control

The Centers for Disease Control is charged with protecting the nation's public health by providing leadership and direction in preventing and controlling diseases and other preventable conditions and responding to public health emergencies.

Major Legislation

The Public Health Service Act, as amended (42 U.S.C. 201 et seq.), provides general authority for the Public Health Service to engage in research and investigations. Pursuant to this authority, CDC engages in public health activities related to food safety and quality.

Organization and Responsibilities

Headquartered in Atlanta, Georgia, CDC has nine field offices outside of Georgia. CDC is responsible for researching, monitoring, and controlling outbreaks of foodborne diseases.

Program Activities

CDC's role relating to foodborne disease is to

- monitor, identify, and investigate foodborne disease problems to determine the contributing factors;
- work with FDA, USDA, the National Marine Fisheries Service, states, universities, and industry to develop control methods; and
- evaluate the effect of the control methods.

Funding and Staffing Levels

For fiscal year 1989, CDC used about $2.6 million for public health activities related to food safety and quality. During the year, staffing related to food safety and quality consisted of about 25 full-time equivalent staff years.

Coordination With Other Federal Agencies

CDC coordinates its foodborne disease activities with FDA, USDA, and the National Marine Fisheries Service.

Critical Food Safety and Quality Issues of the 1990s

CDC stated that despite progress in improving the quality of food and food handling in the United States, foodborne disease remains one of the most common and most important causes of illness and deaths in the United States. CDC estimates that about 6 million cases of illness and 9,000 deaths relating to foodborne disease occur each year.

CDC pointed out that there is increasing recognition that many illnesses with no apparent mode of transmission (and thus not reported as a foodborne illness) are actually foodborne. Also, CDC stated that new foodborne pathogens are being discovered, new food vehicles of transmission have emerged as important causes of disease, previously little-noticed pathogens are proving to cause foodborne disease, and antimicrobial resistance of some foodborne pathogens is increasing.

CDC also stated that the food industry is large, complex, and changing rapidly in the following ways:

- Greater interstate and international movement of animals spreads pathogens.
- Trends in animal husbandry facilitate the spread of disease between animals and encourage the use of prophylactic and therapeutic antibiotics, thereby increasing the antimicrobial resistance of foodborne pathogens.

- Rapid interstate and international distribution of perishable foods eaten without further processing spreads pathogens.
- New foods and new methods of food preparation and storage create unexpected foodborne disease problems.

Federal Trade Commission

The Federal Trade Commission is charged with preventing the free enterprise system from being fettered by monopoly or restraints on trade or being corrupted by unfair or deceptive trade practices.

Major Legislation

FTC enforces the Federal Trade Commission Act (15 U.S.C. 41, et seq.), which prohibits unfair competition and unfair or deceptive acts and practices in commerce.

Organization and Responsibilities

FTC headquarters is located in Washington, D.C. It has 10 regional offices which help carry out investigations and prosecutions for violations of the Federal Trade Commission Act.

FTC's Division of Advertising Practices is the primary office that carries out FTC's food safety and quality mission. The Division's objective is to prevent consumer deception through the misrepresentation of food, drugs, devices, or cosmetics.

Program Activities

FTC headquarters and its regional offices carry out investigations and prosecutions for violations of the act. Examples of FTC investigations during fiscal year 1989 include

- several investigations of advertising claims of companies that test fresh produce for pesticide residues,
- an investigation of ad claims for a home test kit for food impurities, and
- over a dozen investigations of health claims made for food products.

Final orders involving requirements that companies cease deceptive advertising and, in some cases, pay consumer redress were issued against several companies for matters such as the following:

- Unsubstantiated health claims.
- A tap water filter which added a hazardous chemical to tap water.

Litigation is ongoing against a company on the basis of a complaint alleging that the company misrepresented the calcium content and calcium superiority of its cheese and is ongoing against another company on the basis of allegations that its failure to disclose the high salt content of its soup was deceptive advertising because the company promoted the soup as being appropriate for diets to reduce heart disease.

Funding and Staffing Levels

In fiscal year 1989, FTC devoted about 58 staff years to advertising matters, of which over 50 percent were devoted to the food safety and quality area. The advertising matters budget for the year was about $3.28 million of which about $1.99 million (about 61 percent) was attributable to food safety and quality.

Coordination With Other Federal Agencies

FTC and FDA share jurisdiction over consumer deception through the misrepresentation of food, drugs, devices, or cosmetics. Pursuant to an agreement with FDA, FTC has primary responsibility for regulating the truth or falsity of all food advertising, other than labeling. FDA has primary jurisdiction for preventing the mislabeling of foods.

United States Customs Service

The United States Customs Service's mission is to collect revenues from imports and enforce customs and related laws. As the principal border enforcement agency, the Customs Service's mission has been extended over the years to assisting in the administration and enforcement of the requirements of numerous federal agencies, states, local subdivisions, and various international organizations.

Major Legislation

The Customs Service administers the Tariff Act of 1930, as amended (19 U.S.C. 1654), and other related laws. It also assists in enforcing some 400 statutory and regulatory requirements on behalf of about 40 other federal agencies. Examples of the food safety and quality legislation that the Customs Service assists in enforcing include the Federal Food, Drug, and Cosmetic Act; Egg Products Inspection Act; Federal Meat Inspection Act; Poultry Products Inspection Act; and Federal Insecticide, Fungicide, and Rodenticide Act.

Organization and Responsibilities

Headquartered in Washington, D.C., the Customs Service has seven regions covering the 50 states, the Virgin Islands, and Puerto Rico. Contained within these regions are 45 subordinate district or area offices under which there are about 300 ports of entry.

Some of the responsibilities that the Customs Service is specifically charged with are

- assessing and collecting customs duties, excise taxes, fees, and penalties due on imported merchandise;
- interdicting and seizing contraband;
- processing persons, carriers, and cargo into and out of the United States; and
- detecting and apprehending persons engaged in fraudulent practices designed to circumvent customs and related laws and marking requirements for imported merchandise.

Program Activities

The Customs Service performs many services in administering and enforcing the requirements of numerous federal agencies. Examples of the activities performed for the agencies included in our review are

- checking that imported eggs and egg products are accompanied by a foreign inspection certificate,
- verifying that imported milk and cream shipments are tagged and accompanied by the required FDA permit,
- sampling imports upon FDA's request, and
- checking that imports of pesticides are accompanied by a Notice of Arrival form which is sent to EPA.

Commercial entries, which include food items as well as many other types of items, are processed through the Automated Commercial System Cargo Selectivity Module. The primary goal of this module is to facilitate low-risk shipments and target high-risk and trade-sensitive imports, including shipments with other agency requirements, for closer scrutiny.

The Customs Service processes about 8.9 million commercial entries per year, of which about 6 million are processed through the Automated Commercial System Cargo Selectivity Module.

Funding and Staffing Levels

In fiscal year 1989, the Customs Service had about $184.3 million available for cargo examination. During fiscal year 1989, it had congressional approval for about 4,000 full-time equivalent staffing designated for cargo examination.

Coordination With Other Federal Agencies

The Customs Service has a memorandum of understanding with FDA regarding Section 801 of FFDCA, which requires the Secretary of the Treasury (the Customs Service) to deliver import samples to the Secretary of Health and Human Services (FDA) upon request. The purpose of the agreement is to (1) establish a working relationship between the Customs Service and FDA for the cooperative enforcement of Section 801, (2) establish uniformity in the exercise of the import-sampling and refusal authority in the enforcement of section 801, and (3) delegate authority to certain FDA officers to collect samples and issue Notices of Sampling and Notices of Refusal of Admission on behalf of the District Director of Customs.

Major Contributors to This Report

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